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**The Effectiveness Of Foot Orthoses As A Treatment For Plantar
Ulceration In Leprosy: A Study Of The Efficacy, Acceptability,
Appropriateness And Implementation Of A Podiatric Regimen**

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A thesis submitted in partial fulfilment of the requirements of the Open
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ABSTRACT

This was a holistic study. Four themes were investigated to demonstrate the effectiveness of orthotic intervention for plantar ulceration affecting leprosy impaired subjects in India.

1. Efficacy

Efficacy was demonstrated, primarily, through analysis of data pertaining to a controlled trial. Thirty-seven subjects, presenting with leprosy impairments including anaesthesia and plantar ulceration, were fitted with orthoses and allocated to an experimental group. Thirty-four similar subjects, were not offered orthoses and were allocated to a control group. After 8 months 52% of the ulcers presented by Experimental group and 12% of the ulcers presented by the Control group had healed.

The rationale supporting the prescription of orthoses was investigated using the EMED system. It was demonstrated that intervention with orthoses resulted in significantly lower sub pedal peak pressures than intervention with leprosy sandals.

2. Implementation and Sustainability

Ulcer assessment data from March 1994 to January 1995 were used to compare the effects of orthoses supplied by the investigator with orthoses supplied by an Indian technician. The service, evaluated on the strength of these findings, was considered to have been successfully implemented. The analysis of data, collected from January 1995 to December 1995, was used to explain why the service was not sustained at an acceptable level.

3. Acceptability

Interview data were analysed to describe the attitudes of the subjects to the intervention (n = 46). Indications from the analysis were that neither ulcer status (healed or unresolved) nor group allocation (Experimental or Control) affected attitudes towards the intervention. A general indication was that the intervention was favourably endorsed.

4. Appropriateness

Using the Delphi technique ($n = 10$), a consensus on indicators of "appropriate" impairment control measures was sought. Differences of opinion were not resolved, but group priorities were ranked and a polled response was recorded. The results of the study were similar to the criteria suggested by the Delphi contributors.

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CHAPTER 1

PLANTAR ULCERATION AS A SEQUELA OF LEPROSY

INTRODUCTION

In India plantar ulceration is a significant problem for those disabled through leprosy. This chapter introduces an overview of the effects of plantar ulceration which affect the leprosy impaired. It also outlines the development of management strategies since 1960. The rationale for the study precedes a presentation of the project objectives and the study process.

1.1 THE PROBLEM OF PLANTAR ULCERATION

"The pathway to amputation of the leg is littered with bandages and dressings which have deceived both doctor and patient into thinking that by dressing an ulcer they are curing it."

(Brand 1989 p3).

Brand's stark metaphor aptly introduces the gravity of the problem of plantar ulceration. In his judgement, plantar ulceration is one of the most debilitating complications of leprosy after the disease has been arrested. Kumar *et.al.* (1985) observed that it was frequently not the disease itself, but the manifestation of plantar ulceration that causes leprosy sufferers to seek treatment. There is a relatively innocuous aseptic, subcutaneous breakdown that precedes the appearance of frank ulceration. For those with sensate feet, pain would dictate an appropriate response, and the crisis would be resolved. It is in the absence of pain, however, that such an event is a silent prologue to a potentially catastrophic catalogue of complications.

Kulkarni and Mehta (1983) suggested that absorption, which they described as a periosteal osteoclastic action, was a consequence of hyperaemia following ulceration. The osteoporotic state of bone predisposes it to pathological fracture, particularly when pain sensation in the joints is lost. Short foot and tarsal disintegration, two

characteristic features of many Leprosy sufferers, are indicative of these processes.

Those suffering the effects of multibacillary leprosy (see section 2.3.1) may present with osseous deformities that are caused by the infiltration of *Mycobacterium leprae*. The bacillus has demonstrated a predilection for infecting bone but non-specific osteomyelitis is a more common pathology (Kulkarni and Mehta 1983). The invasive and destructive nature of non-specific osteomyelitis has been attributed to secondary infection of ulceration (Brand 1991.) Active secondary infection of ulceration was described by Brand (1991) as causing periostitis. The infection of periosteal tissue or bone frequently leads to sequestration. Brand also suggested that hyperaemia (resulting from plantar ulceration) complicates active infection of bone and contributes a further cause of osteoporosis.

Brand commented that, in the absence of pain response, the spread of infection is enhanced by soft tissue compression and relaxation during walking (1991). The integrity of the fascial compartments to resist the distribution of infective organisms is compromised by sensory loss. His suggestion complemented an earlier explanation given by Enna (1988) who described how the infection of periosteal tissue, or bone, frequently leads to sequestration. Enna described a route by which infection is spread (i.e. to synovial joint spaces along tendon sheathes).

In a study of squamous cell carcinoma in leprosy, Sane and Mehta (1988) suggest that chronic irritation of regenerating epithelium around an ulcer and osteomyelitis with chronic discharging sinuses are two of the predisposing factors influencing the development of carcinoma. They postulated that hyperplasia, influenced by chronic irritation, initiates the regeneration of cells which manifest as papillomatoses adapted to irritation. Continued irritation leads to dysplasia with decreasing cell differentiation and, ultimately, carcinoma.

Complicating this ruinous scenario is the issue of stigma (stigma is discussed in depth in chapter 5). Leprosy is a manifestation of physiological and psycho-social dysfunction that profoundly affects the patient, his or her family and ultimately Indian

society. As long as sufferers' lives are complicated by characteristic deformities, "leprosy" will resist eradication. This is predominantly because the general perception of "leprosy" within Indian communities is confined to conditions associated with characteristic deformities, not to the disease per se. Hansen's disease is curable and may eventually be eliminated as an official public health problem. Unless addressed in the early stages of the disease, the neuropathy associated with the disease is irreversible and the problems related to it will continue. Stigma compounds the physiological disadvantage of those with leprosy impairment. Attempts to disguise ulceration or deformity, not uncommonly, lead to the rejection of treatment. Consequently, the primary causes and the secondary effects of ulceration are not addressed and the spiralling destruction escalates. Considering this catastrophic scenario it is understandable that Behere (cited by Weis *et al.* 1992) should report suicidal ideation in 14 of 24 randomly selected leprosy inpatients in Banares.

1.2 ADDRESSING THE PROBLEM OF PLANTAR ULCERATION

"There is hope of saving the feet of leprosy patients only when it is widely recognised that the whole problem is really one of mechanics, not of medicine. The advice and help of the physiotherapist, the social worker and the shoe maker are likely to be of more significance than the medicine of the physician or the knife of the surgeon."
(Brand 1989 p4)

By the 1960s Brand (1958) had already hypothesised that the aetiology of plantar ulceration in leprosy was probably more closely related to mechanical factors than trophic influences per se. Price (1960) reflected that, until this time, attempts at ulcer treatment included local injections of anti leprosy drugs, Novocaine blockade and local excision of tissue. Like Price, Ross (1960) was also stimulated by Brand's early findings and in the same year as Price published a similar article on the subject of plantar ulceration. Both authors referred to observations that the only consistently effective method of ulcer treatment was plaster cast immobilisation. This they acknowledged was not an innovation. It had been practised and documented as far

back as the Spanish civil war when Trueta (cited by Ross) applied principles of rest and immobilisation in the treatment of war wounds. Acknowledging Trueta, Ross recommended that the treatment of ulceration should follow the following principles:

- "1. Clean the wound*
 - 2. Excise dead tissue*
 - 3. Allow free drainage*
 - 4. Immobilise the part*
 - 5. Prevent secondary infection*
 - 6. Stop reception of the trauma causing the wound.*
- Patients must not walk on wounded feet. "* (Ross 1960 pp 32 - 33)

Both Ross and Price suggested similar management options to frank ulceration (varying periods of plaster casting and bed rest) and these remain the primary approaches to the treatment of plantar ulcers. Price reported using the technique with success and suggested treatment regimes for different stages of ulceration. Ross also used the technique but, in addition, recommended the "Karigiri boot" which has since been recommended by Lal (1974). The Karigiri boot was an innovation developed from a shoe described by Brand in 1959 (Brand 1959). It is constructed on the same principles used for plaster casting but is made using a latex soaked sock instead of plaster of paris. Neither Ross nor Price presented any data to support the anecdotal evidence of plaster cast or Karigiri boot efficacy. Since their pioneering work, however, a number of researchers have made comparative studies of common techniques of plaster casting (Pring and Casiebanca 1982, Kush *et al.* 1985, Kaplan and Gelber 1988, Fritschi 1989, Birke *et al.* 1992). Findings generally concur although authors do differ as to which style of cast is the most beneficial. Pring and Casiebanca (1982) advocated the use of the plaster of paris boot as an appropriate treatment for ulceration. Kush *et al.* (1985) found that plaster cast treatment was more effective if augmented by surgical intervention. Kaplan and Gelber reported rub wounds around the malleolus due to these casts (1988). They also reported high patient dissatisfaction with this technique. Fritschi (1989) suggested caution by recommending that boot casts should only be used to treat simple ulcers.

The disadvantages of plaster of paris casting extend beyond the dissatisfaction

associated with stigma and inconvenience. An obvious physiological risk associated with prolonged immobilisation is osteoporosis, but perhaps a more significant limitation is the temporary nature of healing. Price (1960) observed that unless the predisposing causes of ulceration were addressed it was likely that there would be a recurrence of the ulcer after the removal of the plaster.

Price insisted that the healing of the ulcer was only "*a stage in the treatment*" (1960 p 167). He recommended that all feet compromised by scarring should be fitted with a rigid soled sandal with a soft insole. He designed a wooden sandal with a soft insole to meet these criteria. His rationale for the design was sparse and difficult to support. "*The rigid sole forestalls deep damage between soft tissues and the bony skeleton of the plantar region. The soft insole forestalls damage caused by friction between the skin surface and the immediate points of contact.*"

It is pertinent to pursue these issues in greater depth here because most of the developments in footwear production for the leprosy impaired are based on the criteria of immobilisation and cushioning. Price's assumption that soft material would forestall damage due to friction was at best only partially correct. The effect of cushioning is to reduce force by decreasing the acceleration quotient of the " $\text{mass} \times \text{acceleration}$ " equation describing force. The suggestion that the "*rigid sole forestalls deep damage between soft tissues and the bony skeleton of the plantar region*" has construct validity because the rigid sole he designed incorporated a rocker effect beneath the metatarsal heads.

Translational friction is an essential component of grip and is proportional to the product of the normal force and a coefficient of friction dependent on the properties of two involved surfaces. It may be described as a force acting to prevent relative sliding between two contacting surfaces. Friction acts to stop the moving foot, if internal momentum between bone and soft tissue continues shearing stress¹ results (Rodgers and Cavanagh 1984). Although the concept of immobilisation to prevent shearing stress appears sound it will bare a physiological cost.

¹ Shearing stress acts tangentially to a surface and results in a relative sliding between two surfaces.

Digital dorsiflexion facilitates ankle plantarflexion around a stable forefoot. This does allow a forward thrust, effected by triceps surae. It also extends limb length. As a consequence, the vertical displacement of the centre of gravity after mid stance is reduced, permitting a longer stance phase and an increased step length. Thrust is borne by the metatarsal heads which rotate through between 40 to 60 degrees. When the toes dorsiflex the skin is drawn distally to permit unimpaired motion. This action results in horizontal shear between skin and MTHs which is greatly exacerbated by the posterior thrusting of the skeleton to achieve acceleration for locomotion. By reducing digital dorsiflexion, however, ankle plantarflexion is impeded and a shorter step length, resulting in reduced gait efficiency is a result. Reducing digital dorsiflexion will result in an inefficient appropulsive gait. It will however reduce shearing stress because the centre of gravity never proceeds very much beyond the base of support. Consequently the reaction vector never becomes horizontal and shear is therefore reduced (Inman *et al.* 1981).

In an examination of freshly amputated dissected feet Root *et al.* (1977) observed that in weight loaded specimens rotated to cause sub talar pronation, the metatarsal heads of all feet were observed to rotate in both frontal and transverse planes. Hypermobility of the metatarsals (an effect of aphasic subtalar pronation) will result in shear between the bones and the immobilised soft tissues. Root *et al.* suggest that the resulting abnormal shear produces considerable trauma to the foot. If this is so, it raises doubts about the ability of rigid shoes to address the problem of excessive shear without simultaneous rearfoot control.

The anatomy of the foot pad is structured to accommodate shear (Bosjen-Moller and Jorgenson 1982). Further mechanisms permit an element of sliding between soft tissue structures and bones, these include bursae and synovium encapsulated joints. However if the integrity of these structures is challenged by excessive demand they will demonstrate fatigue. Alternatively if the structures have been damaged and scarring has resulted in the adhesion of skin and fascia, the functional capacity of these features may be markedly reduced. By eliminating the requirement to dorsiflex the toes, therefore, there will be a reduction in stress in the tissues beneath the

metatarsal heads. Although eliminating these sagittal movements may be advantageous, the potential problems associated with uncontrolled frontal and transverse plane movements should also be considered. Such issues are discussed in detail later (see 2.1.10).

1.2.1 FOOTWEAR

Rocker shoes

The most comprehensive study of rocker shoes for leprosy patients was conducted by Bauman *et al.* (1963). Their study focused on kinetic effects and assumed that changes in pressure distribution would alter a predisposition for the foot to ulcerate. Their findings suggest that there are fundamental considerations to be made when designing rocker shoes. These include the angle of rocker, the anteroposterior position of the rocker axis and the orientation of the rocker axis with the shoe. What arises from reviewing the literature relating to rocker shoes is that there is no clear consensus on these criteria (Simms and Birke 1985, Nawoczenski *et al.* 1988, Schaff and Cavanagh 1990).

Clearly, positioning of the rocker must depend on identifying vulnerability and individual anatomy. It has been established that by positioning a rocker distally under the metatarsal heads (MTHs), pressure under the hallux is reduced compared with reductions attributed to a rocker positioned 1.7 cm behind the MTHs. (It seems highly dubious that a rocker might be placed with such precision.) The more proximal placement of the rocker, however, showed advantages over distal placement where the objective was to reduce pressure over the second MTH (Bauman *et al.* 1963).

A reduction in pressure under the medial and central MTHs with a rocker positioned behind the MTHs was a recurrent finding (Coleman 1985, Simms and Birke 1985, Coleman 1987, Nawoczenski *et al.* 1988, Schaff and Cavanagh 1990). However, a comparable reduction in pressure on the lateral forefoot has not been reported. Some investigators have recorded an increase in pressure under the fifth MTH (Schaff and Cavanagh 1990). The elevated pressure, or insignificant reductions in pressure on the fifth MTH, are probably due to rockers being positioned nearer the fifth MTH which

lies in a proximal position relative to other MTHs.

Increased heel loading and force impulse (the product of force and the duration of the application of force) are widely reported. Such findings suggest that rockers are contraindicated for individuals with foot wear that does not incorporate a heel counter. The confinement of the heel pad should enhance the effect of shock absorbency and may therefore compensate for the increased and sustained forces that are applied to the heel when a rocker is used.

The height of the rocker is a critical factor. Bauman *et al.* (1963) opined that if the anterior edge of the rigid shoe makes ground contact at propulsion there will be considerable force applied to the forefoot. This effect is the result of an alteration in the order of leverage with the distal displacement of the axis of motion.

The structure of the midfoot is also at risk where dorsiflexion at the metatarsophalangeal joints (MPJs) is eliminated. The lever arm that normally extends to dorsiflex the toes at the MPJs is extended to dorsiflex the ankle which, during propulsion, is being used to apply a plantarflexion thrust. The talar navicular articulation will present the first occasion of least resistance and excessive opposing forces may cause the dorsal edges of the opposing bones to impinge on each other thereby potentiating trauma. This may be a significant consideration for neuropathic feet vulnerable to tarsal disintegration.

It has been reported that an effect of rocker bottom shoes is the reduction of shearing stress (Pollard *et al.* 1983). Significant reductions in longitudinal shear have been demonstrated when a shoe, incorporating a "deep rocker" behind the MTHs was compared with other types of footwear. Of particular interest in Pollard's study was the observation that 70% reduction in shear under the central MTHs was not complemented by a reduction in vertical pressure.

Further rationale for the use of rocker shoes was that the rigidity and alternative geometry of the shoe would alter gait to the benefit of the injured foot. Schaff and Cavanagh (1990) demonstrated this effect by recording that all subjects wearing

rocker shoes in their study took shorter steps (reduced by 8cm) and increased rate of cadence by six steps a minute. Zhu *et al.* (1991) reported findings that support Brand's hypothesis that a shuffling gait would reduce peak pressure. They later presented evidence to indicate that an increased cadence was associated with increases in peak pressure (Zhu *et al.* 1995). Controlled cadence (usually timed by metronome) does standardise conditions for data collection. However, it reduces the validity of investigation as it will not reflect normal kinematic induced force distribution.

There can be little doubt that rocker shoes may significantly improve the prospects for foot salvage. Although the author would not question the face validity supporting the application of rocker shoes there are other considerations beyond the academic integrity of the model. The cost of producing and supplying effective rocker shoes is prohibitive. It is widely accepted amongst impairment control specialists that the provision of free footwear is counter productive. Unless some contribution to the cost is made, footwear is not generally respected or adequately cared for. In India distinctive footwear is a major stigmatising agent and patients are understandably unwilling to pay for footwear meeting such low patient acceptance.

Sandal design

Developments toward producing effective sandals, with high patient acceptability, is an objective espoused by ILEP². Enna *et al.* (1976) presented a sandal designed for leprosy impaired patients in America. He sought to produce a sandal incorporating a moulded polyethylene insole, supported by a mixture of sawdust and latex on a neoprene crepe sole. This approach could be useful for patients with an apropulsive gait, but it may be contra-indicated for more normally functioning feet. The foot is a dynamic structure, it shortens and lengthens during the normal stance phase of the gait cycle. Unless the foot is immobilised with a rigid sole incorporating a rocker, a close fitting moulded innersole could be counterproductive. Enna's choice of expanded polyethylene is not appropriate unless resources permit frequent change because the material compresses within a relatively short period.

² ILEP is an international federation of autonomous anti-leprosy associations.

Patil *et al.* (1986) also based their recommendations on static studies. However, their recommendations were that microcellular rubber, of varying degrees shore, should be used as components to form a composite sandal insole. Their recommendations are based on findings relating to one atypical subject and whilst demonstrating the requirement to address individual needs their recommendations may not be applicable for the general population of leprosy sufferers.

Attempting to address the problem of stigmatising footwear, Dr Antia designed an extruded plastic sandal which was similar in appearance to sandals obtainable in local markets throughout India. This sandal incorporated an upper to hide moderate deformities, a heel counter and a steel shank beneath an 8mm, 18 shore EVA sponge. These sandals were evaluated by Kulkarni *et al.* (1990) who used Harris mats to demonstrate reduced loading. Linge (1995) used the EMED system to demonstrate that the "Antia" shoe was associated with a 19% reduction in peak pressure for the mean of ten plantar sites examined. Kulkarni *et al.* (1990) reported problems associated with the dorsum of the foot where the plastic had caused cuts. There were further problems with the fittings on the shoe (buckles snapped off).

The rationale for introducing a steel shank is to limit dorsiflexion at the metatarsophalangeal joints (MPJs). By limiting digital dorsiflexion ankle plantarflexion is jammed. A large dorsiflexion moment is created around the ankle. As the ankle reaches the limit of its range of motion, force is translated forward into the subtalar and midtarsal joints where its effects on the talonavicular and calcaneocuboid joints may be substantial. Consideration must be given to the potential for precipitating tarsal disintegration.

1.2.2 ALTERNATIVE APPROACHES

Some investigators have preferred surgical intervention to try and address the problem of foci of high pressure (Bhasin and Antia 1972, Srivastava and Kesarwani 1976, Kao and Jena 1988), however, Brand (1988) indicated that unless the underlying mechanical cause is addressed, ulcers will recur. It is likely that by

removing one area associated with high peak pressure an alternative area will be exposed to the forces that caused the earlier problem. Surgery to alleviate the major predisposing causes of ulceration (sensory loss) may prove to be more beneficial. Palande and Azhaguraj (1975) investigated the effects of posterior nerve decompression as an approach to the problem of ulceration and were encouraged by their findings. There is currently a major multi centre study being conducted in India to investigate the effects of the procedure. Rao *et al.* (1987) demonstrated that by effecting decompression of the posterior tibial nerve, there was an increase in sweat secretion. This they took to be objective evidence of a restoration of autonomic function. The success of the procedure was limited to patients presenting with neuropathy of up to one year in duration. Their findings lead them to conjecture that the procedure could lead to a decrease in the incidence of deep fissuring, which is a common cause of ulceration.

General Considerations

Maintaining or supplementing the integrity of the skin on the sole of the foot is considered a fundamental measure to prevent ulceration (Watson 1986). Foot soaks have been advocated as a simple self administered measure that all leprosy impaired subjects should practise (Fritschi 1969, Jopling 1978, Bryceson 1979, Watson 1986). A weak comparative study of the effectiveness of different foot soaks was undertaken by Premkumar *et al.* (1990). Apart from that study and anecdotal accounts there is no evidence to validate the measure. Similarly, whilst the application of oil rubs has face validity there is, as yet, no scientific evidence to support the measure.

Walton *et al.* (1986) conducted a small investigation to compare the effects of zinc oxide impregnated tape with conventional antiseptic soaked gauze as dressings for ulcers. The indications were that zinc oxide tape may be more beneficial than conventional dressings but the study was too small to demonstrate statistical significance. This method was recommended as a first line treatment for simple ulcers³ and did not presume to address predisposing factors.

3 Simple ulcers involve only skin and subcutaneous tissue. They are not complicated by necrotic bone, or fibrous tissue and are not obviously infected.

1.3 STUDY RATIONALE

In some respects the dynamism demonstrated in the early 1960s appears to have lost momentum. Limited primarily by resource restrictions, the options available to assist those suffering the effects of leprosy seemed to have reached an impasse. This study is a response to the challenge imposed by such restrictions.

In the West, economic pressures and expectations of quality care have driven extensive research into diabetic impairment control. It is to be hoped that where advances have been made, they can be applied to health care situations in the developing countries. Diabetic neuropathic ulceration has been the focus of many studies and the literature abounds with accounts of varying approaches to treatment. However, caution is suggested in drawing too close a parallel between diabetic and leprosy neuropathy. The loss of sensation and mechanical causation are perhaps the only common factors linking these pathologies. Features compounding diabetic neuropathic ulceration, including angiopathy and impaired healing rates, are not common features of leprosy neuropathy. The rationale for an alternative approach to leprosy ulceration, however, is principally sociological. The availability of resources and facilities in an Indian leprosy hospital and the socio-economic status of leprosy sufferers are the parameters within which therapies are required to be developed (Miles 1989, Kenkre 1993).

Findings recorded by the WHO (1991) demonstrate that together, India, Indonesia, Brazil, Nigeria and Myanmar, contribute 82% of all registered cases of leprosy. Prevalence figures demonstrating registered cases in India are recorded as 2-2.9 per 1000 (WHO 1991), but prevalence rates of 5-6 per 1000 cited by Weiss *et al.* (1992) may be a more accurate reflection of the extent of the problem as social and cultural restraints prevent many from seeking treatment. These figures indicate that in India, with a population approaching 900,000,000, there are between 1,800,000 and 5,400,000 people suffering from leprosy or its secondary effects. Brand's (1983) estimate that 33.3% of this number suffer foot pathology secondary to the disease suggests that between 600,000 and 1,800,000 people in India present with

compromised feet as a result of leprosy.

India presents a society where many millions of people aspire to little more than survival and the scale of mortal fragility challenges the imagination. In this context a despised disease, the effects of which probably affect 1% of the population, is not generally considered a priority issue. The limited material, social and academic resources available are inevitably channelled primarily into areas perceived as exhibiting a higher social demand.

1.4 PROJECT OBJECTIVES

The principal project objective was to resource an Indian leprosy hospital with a service which would augment current initiatives to treat plantar ulcers. Pragmatism dictated that the principles of a biomechanical approach to ulcer care should be adapted to conform to existing resource limitations. Only readily available materials and local facilities would be used. The hospital had no provision for a podiatrist who would normally provide such a service in the West. It was considered, therefore, that essential skills and knowledge should be transferred to key personnel. The policy was to resource a senior medical figure with relevant podiatric theory, and to train auxilliary personnel in the practical aspects of orthotic manufacture and supply. With such a team, it was considered that the hospital would be able to provide an aspect of podiatric care without making excessive additional demands on any one person. This contingency strategy was planned to ensure that, should orthotic intervention demonstrate efficacy, an infrastructure to sustain a service would have been established.

1.5 STUDY AIMS

The primary aim of this study was to investigate whether the introduction of foot orthoses could present a valid contribution to current leprosy impairment control initiatives. Through analysis of pertinent quantitative data and field records, it was aimed to describe a model that could be used if a similar service was to be considered elsewhere. A further aim was to present clinical and laboratory evidence to investigate the general rationale for podiatric orthotic prescription.

The acceptability of the approach adopted was to be assessed using interview schedules. A secondary aim of this procedure was to further current insight into the psycho-social effects and consequences of leprosy impairment.

1.5.1 DEFINITION OF PARAMETERS

"Effectiveness" describes a consequence, which has become operative. The term "operative" is defined as *"efficacious; practical not theoretical or contemplative."* (Oxford Dictionary 1984).

To demonstrate "effectiveness" it was decided to address four criteria:

- | | | |
|----|-----------------|---|
| 1. | Integration | The ability to implement and sustain the regimen. |
| 2. | Efficacy | The ability to produce an intended or appropriate effect. |
| 3. | Acceptability | Value accorded by recipients. |
| 4. | Appropriateness | Suitability within the socio-cultural context and compatibility with impairment control objectives. |

On the condition that sufficient evidence is presented to satisfy the above criteria, the treatment may be considered "effective".

1.5.1.1 The efficacy of podiatric orthoses

Efficacy, acceptability, sustainability and appropriateness are interdependent. The

effectiveness of the treatment is no less dependent on the acceptability of the orthoses by the study population than is efficacy. It is the author's contention, however, that the internal validity of the study is dependent, primarily on the demonstration of efficacy. Efficacy is demonstrated, initially, through the analysis of data pertaining to a controlled trial (chapter 2). Further support is contributed through a section of the study which addresses the issues of efficacy and implementation simultaneously (chapter 4).

1. Chapter 2 opens with a description of the collaborating institutions and project personnel. (Section 2.1.1.)
2. Experimental design and ethical issues that influenced the course of the project are discussed. (Section 2.1.2.)
3. Methods of assessment, including rationale and limitations, are detailed. (Sections 2.2.)
4. Data describing assessment findings, during the period from July 1993 to March 1994, are presented and analysed. (Sections 2.3.)
5. The discussion places the results in the context of the established literature. (Section 2.4.)

1.5.1.2 Kinetic studies

The rationale supporting the prescription of orthoses is investigated using the EMED system of sub pedal pressure analysis. Data collected at the University Department of Orthopaedic and Accident Surgery, Royal Liverpool University Hospital, are presented, analysed and discussed. (Chapter 3)

1.5.1.3 The implementation and sustainability of a podiatric orthotic service

The process, through which the service was instituted, is described. Further ulcer assessment data is analysed to investigate the efficacy of the treatment. Data analysis also contributes to an investigation of the effectual implementation and sustainability of the regimen.

1. Data describing assessment findings during the period from March 1994 to January 1995 are presented and analysed. This data is used to compare the effects of orthoses prescribed and supplied by H. Cross with orthoses prescribed and supplied A. Dey. The implementation of the service is evaluated on the strength of these findings (sections 4.3 to 4.4).
2. Issues relating to the efficacy of the intervention are also discussed following analysis of the data.
3. Data collected in January 1995 is compared with data collected during November and December 1995. Findings, augmented by observations from field notes are used to identify issues relating to sustainability (section 4.5).

1.5.1.4 The acceptability of foot orthoses

The development and execution of an interview schedule are described. Data describing pertinent subject opinions and experiences are declared to support the suggestion that the treatment was acceptable (Chapter 5).

1. References from the literature are used to develop a profile of the social and cultural context in which the study was undertaken (section 5.1).
2. Methodological and schedule design issues are discussed (section 5.2).
3. Schedule data are presented and analysed. The acceptability of the intervention is inferred from the attitudes suggested in the results (sections 5.3 to 5.5).

1.5.1.5 The appropriateness of foot orthoses

The parameters by which "appropriateness" may be gauged in the Indian context are sociologically and culturally specific. A consensus on indicators of "appropriate" impairment control measures in India was sought. Indications inferred from all findings are compared with the consensus of appropriate impairment control measures declared by senior Indian field workers. Compatibility with the criteria may suggest that the treatment was appropriate (Chapter 6).

1. References from the literature are used to develop a profile of the current status of leprosy control initiatives in India (section 6.1).
2. The design and implementation of a Delphi Investigation are described (sections 6.2 and 6.3).
3. The findings declared are used as a frame of reference for the assessment of the appropriateness of foot orthoses as an impairment control measure for Indian leprosy impaired subjects (sections 6.4 and 6.5).

1.5.1.6 Conclusion

The project will be summarised. Pertinent issues will be expressed and recommendations will be suggested.

CHAPTER 2

THE EFFICACY OF PODIATRIC ORTHOSES

AIM

The efficacy of customised orthotic intervention will be considered following analysis of data describing changes in ulcer area and morphology as effects of the orthotic intervention.

Process \ Content:

1. Introduction

- 1.1. Details of collaborating bodies, project personnel and the leprosy impaired population at Kondhawa are presented.
- 1.2.. Ethical and experimental design issues.
- 1.3. The rationale for sensory testing and ulcer assessment is introduced.
- 1.4. The rationale for orthotic intervention is introduced.

2. Method

- 2.1. Methods of data collection and statistical analysis.
- 2.2. Details of the sample subjects.
- 2.3. Assessment procedures and supply of orthoses.

3. Results

- 3.1. Results relating to the initial eight months of the trial are declared.

4. Discussion

2.1 INTRODUCTION

2.1.1 THE COLLABORATING INSTITUTIONS AND PROJECT PERSONNEL

Medical facilities and rehabilitation enterprises

The "Kondhawa Leprosy Home" was founded by the Scottish Mission in 1910. In 1942, when the superintendent of the home (Dr Simon) was murdered by the patients, the mission handed over the home to the then Bombay Government. In 1956 the government handed over the home to the Poona District Leprosy Committee for management and development. As the Founder President Dr N.J. Bandorawalla raised the number of inpatients to 300 and was responsible for an extensive development of facilities. The "home" pattern, however, did not change until 1966 when Dr J. Mehta (son in-law of Dr N.J. Bandorawalla) was elected president following the death of Dr Bandorawalla. With an average 425 inpatients, Dr Bandorawalla Leprosy Hospital is currently resourced with a reconstructive surgery unit, a physiotherapy department, an orthopaedic appliance department and extensive outpatient facilities. During the period 1970 -1974 the Poona District Leprosy Committee (P.D.L.C.), supported by the Social Rehabilitation Services of the Department of Health Education and Welfare, Washington, USA undertook a project to ascertain the rehabilitation potential of debilitated leprosy patients (Mehta *et al.* 1992). Acting on recommendations drawn from the project, a broader socio-medical approach to the treatment of leprosy was instigated. It was decided that the established medical services were to be enhanced by rehabilitation programmes. The *Mehta Co-operative Rehabilitation Model* was established to integrate training and rehabilitation programmes for leprosy patients, other physically disabled people and socially disadvantaged but able bodied people.

A Common Vocational Training Programme For The Handicapped, conceived in 1979, was implemented to train and encourage the handicapped to establish independent co-operatives. On completion of the initial three years of training a co-operative society was formed and registered under the title, *Dr Minoo Mehta*

Apangoddhar Sahakari Audyogic Utpadak Sanstha Maryadit.

The enterprises that have been established by the society include engineering components works, power loom weaving, agricultural units, timber milling and crate construction. These enterprises are situated in the Kondhawa and Bhosari districts of Pune where many of the patients have established homes in the community. Others live in colonies that have developed in proximity to Dr Bandorawalla Leprosy Hospital and the Kondhawa enterprises. Individuals, selected mainly on grounds of particular social vulnerability or outstanding aptitude are offered employment by the hospital in its various departments. Some of these individuals are also members of the society and live in colonies maintained by the P.D.L.C. Others live at the hospital.

Project personnel

J.M. Mehta (Advisor and facilitator of technical support)

Honorary President of Poona District Leprosy Committee

General Surgeon

M.B.B.S. Bombay University, India

M.S. (General Surgery) Bombay University

S.B. Sane (Field Advisor)

General Surgeon

M.B.B.S. University of Pune, India

M.S. (general surgery) University of Pune, India

V.N. Kulkarni (Field Co-Ordinator)

Physiotherapist

BSc (P.T.) Government Medical College, Nagpur, India

Post Graduate Certificate and Diploma in Rehabilitation from All India Institute of Physical Medicine and Rehabilitation, Haji Ali, Bombay, India

A. Dey (data collection and technical support)

Physiotherapy technician

Formal education terminated when leprosy was diagnosed in 1970. Mr. Dey received training at Dr Bandorawalla Leprosy Hospital.

2.1.2 EXPERIMENTAL DESIGN AND ETHICAL ISSUES

The first protocol, upon which the project was based, presented a method to investigate the dependency of plantar ulceration on foot function. A further objective was to implement a sustainable service that could be incorporated into the existing infrastructure at Dr. Bandorawalla Leprosy Hospital. To accomplish these objectives, functional foot orthoses were to be manufactured from locally available materials and resources⁴. Sample selection, assessment procedures and supply of orthoses was to run concurrently with staff training.

Having identified willing subjects, biomechanical foot examinations were conducted on the first five subjects. The examination followed procedures suggested by Root *et al* (1971). A non-weight bearing examination included identification of any structural deviations from normalcy (the foot was examined with the subtalar joint in its neutral position). The examination also considered the range and quality of motion of joints distal to the subtalar joint. A weight bearing examination sought to ascertain the extent and direction of subtalar joint deviation from its neutral position (a neutral position is considered to be the optimal alignment for the joint at mid stance). The examinations were conducted by the author and were observed by V.Kulkarni (physiotherapist). Functional orthoses were prescribed and manufactured by me. The process was observed by A.Dey (physiotherapy technician) and R.Karunakaran (prosthetics technician).

Of the initial five subjects, three wore micro-cellular insole sandals and two wore trainers. New sandals were issued to subjects who routinely wore them (these sandals

4. Using, predominantly, off-cuts of micro-cellular rubber (M.C.R.) and vinyl soling material from the sandal making enterprise, sufficient material was found to construct a number of component parts. It was planned to assemble components to meet the varying requirements of individuals.

are manufactured at the hospital). The functional orthoses were either adhered to the sandals to prevent displacement, or positioned in trainers. Subjects were advised to observe a basic "wearing in" procedure: i.e. to wear their old sandals for half the day and the new "modified" sandals for the remainder of the day. The two subjects who wore trainers were likewise advised to remove the orthoses after having worn them for half a day. These subjects were requested to present for assessment after a one week period. The rationale for implementing a "wearing in" period different from that usually prescribed was that most orthoses would be adhered into sandals. The preferred method⁵ was therefore not practicable. It had been considered that the request that subjects should, initially, wear the modified sandals for half a day could have been problematic. The issue was, however, not considered to present an insurmountable difficulty. In retrospect this assumption was probably incorrect.

After five days two subjects returned complaining of pains associated with the devices. One presented with synovitis of the posterior tibialis tendon whilst the other presented with groin strain. Following examination, it was diagnosed that both conditions were associated with wearing the functional orthoses without adequate "wearing in" procedure. Two other subjects also returned complaining of pain. One drew attention to mid tarsal pain and the other to subtalar pain. These conditions were also attributed to inadequate "wearing in" procedure. Following these observations, the fifth subject was requested to present for examination. He complained that the sandals would not contain his feet. On examination it was observed that the high medial posting, of the devices supplied, caused his heels to be displaced from the sandals laterally. A strap that passed around the ankle did not restrain the heel adequately.

These early indications suggested that the "wearing in" advice was inadequate and that the design features of the sandals were incompatible with the requirements of the functional orthoses. These findings indicated that it would be unethical to continue without modifying the research requirements. Consequently, the protocol was

5. Normal recommendations are that functional orthoses should be worn for periods increasing from one hour by increments of an hour per day until the subject is wearing the orthoses for a minimum of seven hours per day.

reviewed. Following discussion with the project supervisor and advisors at Dr. Bandorawalla Leprosy Hospital, fundamental changes were recommended and applied.

2.1.2.1 The revised protocol

It was decided that functional orthoses could only be supplied to subjects meeting the following criteria:

Subjects should wear shoes, not sandals.

Subjects should have occupations sufficiently flexible to permit "wearing in" requirements.

Subjects should possess sufficient intellect to understand the required "wearing in" procedure.

Dr. Jadhev (Senior Medical Officer, Dr. Bandorawalla Leprosy Hospital) did suggest that the institution should provide all subjects with canvas shoes. This offer was declined because it was felt that although a supply of shoes would provide a temporary solution to the problem it would not have satisfied the objective to implement a sustainable service. This was confirmed by Dr Jadhav who would only undertake to supply canvas shoes for the initial period of data collection. Following further discussion, it was reaffirmed that the principal objective of the project was to address the problem of ulceration within the limits of the physical and socio-cultural demarcations of the population.

A limitation of the former protocol had been that only subjects with minimal structural and functional abnormality could be considered. A consequence of reappraisal was the suggestion that the study population should be redefined. By considering all leprosy impaired subjects with ulcerated, neuropathic feet the relevance of the research would be widened considerably. It was considered that, hypothetically, the diverse podiatric needs of this considerable population could be met using a wide range of orthotic devices. This consideration did not exclude the prescription of functional devices, but extended the orthotic management options to include palliative devices and devices that would address both functional and

palliative requirements. Based on experience, it was considered that such devices could be accommodated in the standard styles of leprosy sandals as well as most other types of foot wear in common use.

Following recommendations that arose from the reappraisal of the project, the criteria for subject inclusion was extended. Where functional orthoses were not deemed suitable, stance measurements were not recorded. Apart from this alteration, the revised protocol necessitated little change to established assessment procedure.

On the 26th of July 1993, subject assessment, supply of orthoses and data collection proceeded. A. Dey was present at all assessments and observed the prescription and fitting of orthoses to all experimental group subjects.

Sandals

It was recorded that attempts to fit orthoses into some existing sandals met with difficulties. There are two styles of sandal most commonly produced at Dr. Bandorawalla Leprosy Hospital. A cobbler and assistants manufacture and fit sandals to suit individual needs. The "Bata" style sandal (see Fig. 1.) is generally favoured by the population at Kondhawa because it is considered less stigmatising than the "Y" style sandal (see Fig. 2). The "Bata" sandal has no adjustable straps over the dorsum of the foot to permit tightening or loosening. These sandals are occasionally made to fit a foot dressed with bandage. Consequently, when the bandage is discarded the sandal no longer fits (see Fig. 3). The "Y" style sandal does have adjustable straps. However when fitted over a bandaged foot these straps are frequently tightened close to their limit. A similar problem can occur with these sandals when bandages are discarded.

The material used to manufacture the sandal soles was discarded vehicle tyre. Using the wall of the tyre, appropriate sized lengths were ground to a thickness of approximately 1cm. This material is hard wearing and inexpensive. Although such features are highly desirable, there are mechanical features of the material that contraindicate its use for sandal manufacture. Although grinding does serve to flatten

the material this has been noted as a temporary effect. After a period of time the material distorts (this may be a response to an elastic memory) causing the sole of the sandal to buckle. There are two major, interdependent effects of this occurrence:

1. The foot is challenged by inconsistent and unstable forces that can adversely affect the kinematic function of the foot.
2. The restraining straps lose their integrity and the foot is further challenged by a demand to maintain contact with the unstable innersole.

Having noted this problem, the issue was discussed with senior medical personnel at Dr. Bandorawalla Leprosy Hospital. Consequently, on the recommendation of Dr. Sane (Orthopaedic surgeon), Dr. Mehta (Honorary President P.D.L.C.) ordered the abandonment of the material and sanctioned the use of an alternative. The alternative was a vinyl soling material used by Indian shoe manufacturers. Although not as hard wearing and more expensive, it does not exhibit the effects demonstrated by used tyres. The reduced longevity of the vinyl soling material may, however, be a positive factor. It had been noted that the leather uppers of the sandals' generally appeared to lose their integrity before the sandals' soles were worn out. Without adequate restraint feet are inclined to be displaced from the sandal, most commonly at the heel (see Fig. 3). The foot is compromised because the heel is exposed and unprotected; furthermore, the kinematic function of the foot will be compromised. A requirement to renew sandals before the leather straps had lost their integrity should be viewed favourably.

Figure 1

The "Bata" sandal.

This style of sandal is more popular because it is considered less stigmatising. A fundamental problem with the design is that it is not adaptable. If incorrectly fitted it can prove hazardous.



Figure 2

The "Y" sandal

This style of sandal can be tightened over the dorsum of the foot. It is not favoured as it is considered stigmatising.

Figure 3

After bandages are discarded, or with prolonged wear, the sandals no longer fit and the foot is vulnerable to trauma.



Sandals are frequently supplied whilst the patients are using gauze bandage dressings. When the dressings are discarded the sandal no longer fits correctly and both the dorsal and plantar aspects of the foot are rendered vulnerable.



2.1.3 SENSORY LOSS

As an introduction to the rationale for sensory testing, a contextual review of leprous neuropathy is presented. The aim in so doing is that a frame of reference will be provided to support conjectures and inferences that may be made. Leprous neuropathy is a complex issue and the rationale for sensory testing is clarified by consideration of the neuropathy that characterises the different classifications of the disease.

2.1.4 NEUROPATHY

Jopling and Mc Dougal (1988) suggested that the reasons why classification was rational is that it indicates which patients are infectious and what the prognosis for the individual is likely to be. It is also essential if correct therapy is to be prescribed. In the context of this study, the most pertinent point is that classification gives some indication of the probable type and extent of nerve involvement. When comparing samples, therefore, classification should be considered.

Table 1: Ridley-Jopling Classification (From: Jopling and McDougal 1988 p43)

Observation	TT	BT	BB	BL	LL
Number of lesions	Usually single	Single or few	Several	Many	Very many
Size of lesions	Variable	Variable	Variable	Variable	Small
Sensation in lesions	Absent	Diminished	Moderately diminished	Slightly diminished	Not affected
Surface of lesions	Very dry scaly	Dry	Slightly shiny	Shiny	Shiny
AFB in lesions	Nil	Nil or scanty	Moderate numbers	Many	Very many plus gobi
lepromin test*	(+++)	(+ or ++)	Negative	Negative	Negative

* See Jopling and McDougal 1988 p.p. 56 - 59

2.1.4.1 Neuropathy in tuberculoid leprosy (TT)

The most significant changes in tuberculoid leprosy involve the cutaneous and subcutaneous nerves. These structures are invaded and destroyed beyond recognition by epithelioid granuloma. Surviving nerves usually demonstrate swelling with infiltration of the perineurium and extension of granulomae into the endoneurium.

The destruction of dermal nerves explains the localised anaesthetic patches, sometimes the only indication of polar tuberculoid leprosy. Dermal lesions usually appear as single plaques that may appear anywhere except the scalp, groin, axillae or perineum. Autonomic loss is a feature of tuberculoid lesions where axon reflex and sweating are found to be absent (Sabin and Swift 1984, Jopling and McDougal 1988).

The Sabin and Swift hypothesis

Sabin and Swift (1984) suggest that the bacteria enter the host at the affected area where cellular response of the host localises the infection. They suggest that skin lesions and nerve involvement are simultaneous events and that nerve involvement may be limited to the section of nerve adherent to the segment of involved skin. The involvement of nerve trunks, being in proximity to skin lesions is secondary to cutaneous nerve involvement. Nerve thickening in the region of the lesion may be felt as being smooth or irregular. They postulated that granulomae may either spread through subcutaneous tissue, or along nerve branches to respond to further bacilli invasion of larger nerves. The theory that infection is made through skin contact, is contested by Jopling and McDougal (1988).

The Jopling and McDougal hypothesis

Jopling and McDougal (1988) suggest that skin lesions are likely to develop only if the bacilli, or its antigens, escape from the nerve into the surrounding tissue. Their theory of nerve destruction is based on *M. Leprae* predilection for targeting the Schwann cell. The Schwann cell is infiltrated and slowly destroyed (mitosis by each bacillus takes 12-13 days to complete). Intraneural infection spreads when bacilli are liberated by exhausted Schwann cells and continues until immune response

recognition. Nerve damage is an inherent effect of host response and is not related to massive proliferation of bacilli. An intense response to infection may lead to necrosis and the development of nerve abscesses. Where a nerve trunk is affected the sensorimotor deficit will be superimposed giving rise to the localised mixture of neurological defects characteristic of tuberculoid leprosy. They record that biopsies of tuberculoid lesions revealed foci of tuberculoid granulomae around neurovascular elements. Examination of foci revealed zones of lymphocytes coating clusters of epithelioid cells. They postulate that it is these foci that invade the papillary layer of the dermis and may erode the basal layer of the epidermis. Their theory is supported by the observation that bacilli are not found in this region.

Research continues and no clear consensus has evolved to support either hypothesis (Barros *et al.* 1987, Shetty *et al.* 1988).

2.1.4.2 Neuropathy in lepromatous leprosy (LL)

Symmetrical and bilateral sensory loss of lepromatous leprosy is explained by the massive and widespread distribution of bacilli and is clearly related to body temperature. Sabin and Swift (1984) presented repeated patterns of surface temperature obtained by thermographic scanning of normal subjects. By comparing gradients between different body temperatures and the evolution of neurological deficit a clear relationship between the usual distribution of surface temperatures and sensory loss was demonstrated.

Sensory loss is clearly apparent in the cooler regions first with the pinnae of the ears presenting the earliest deficit. Progression is marked by a spread from the dorsal surfaces of the hands and feet, dorsomedial surfaces of the arms and anterolateral aspects of the lower limbs. If untreated, extension of sensory loss to less cool areas proceeds to affect almost the entire surface of the body. Although lepromatous leprosy is commonly described as affecting glove and stocking sensory loss, Sabin and Swift (1984) and Jopling and McDougal (1988) indicate the inaccuracy of this description. Sensory loss is symmetrical and bilateral but progression is patchy and

the loss of sensory modalities in the extremities may not be simultaneous.

The regions characteristically spared sensory loss include the webbing of the toes, popliteal fossa, the inguinal creases, axillae, sternal areas and a strip of variable width up the centre of the back from the intergluteal fold to the neck. There is an abrupt end to insensitivity at the hairline where there is an increase of between 1.5° and 3° C in temperature as an effect of hair cover (Sabin and Swift 1984).

There is no pure motor neuropathy in leprosy. Paralysis reflects the involvement of mixed nerves where they lie close to the surface of the body. The proliferation of bacilli at these sites causes an enlargement of the nerve which then predisposes it to compression and trauma thereby imposing a secondary pathological effect. An interesting observation is that even with a fully developed pattern of paralysis muscle spindle and golgi tendon reflex activity are not affected. This explained by the knowledge that afferent fibres from receptors run with motor fibres at a deeper level than dermal nerves (Sabin and Swift 1984).

Due to depressed cell-mediated immunity in lepromatous leprosy the haematogenous spread of the bacilli allows the unchecked proliferation of bacilli. Bacilli have been identified in most tissues and organs but the most significant effect of infection results from *M. Leprae* affinity with the Schwann cell (Jopling and McDougal 1988). It has been recorded that nerve damage is slower to become apparent than in other forms of leprosy. Despite massive concentrations of bacilli, nerve endings and nerve trunks are frequently shown to maintain their structure (Jopling and McDougal 1988). However, the lepromatous infiltrate consisting of bacilli congested histiocytes, causes a splitting of the perineurium. A characteristic "onion peel" appearance of the perineurium has been described (Enna 1988).

Jacobs *et al.* (1987) suggested that it was not surprising to identify demyelination as the major change in fibres of leprosy nerves as leprosy neuropathy is a chronic syndrome. Even where there is evidence of considerable axon loss, demyelination was

still found to be the predominant change. Demyelination was observed as affecting fibres of all sizes and was frequently associated with a "folding or wrinkling" of the myelin sheath.

The integrity of the intraneural environment is thought to be breached as a consequence of the multiplication of bacilli in the perineurium and repair responses to associated tissue damage (Pearson and Ross 1975, Chandi and Chacko 1987) Sabin and Swift (1984) reported that masses of bacilli have been located between the perineurium and endoneurium fully encircling the endoneurium. Bacilli have also been identified in the endothelium of endoneurial blood vessels (Chandi and Chacko 1987, Shetty *et al.* 1988).

Whilst bacilli continue to multiply within Schwann cells and perineurium others are dispersed with the destruction of the same. Liberated bacilli are engulfed by histiocytes in which they are not destroyed. In tuberculoid leprosy histiocytes having destroyed the bacilli remain in situ to become fixed epithelioid cells. By contrast however, in lepromatous leprosy, the histiocyte becomes a vehicle that transports multiplying bacilli to other regions of the nerve or other tissues. It is these cells that are known as lepra cells, carrying masses of bacilli collectively called globi (Jopling and McDougal 1988).

Even in late stages of the disease, when the epineurium and surrounding blood vessels have been heavily infiltrated, the fascicular structure of nerve trunks may stay intact. However, endoneurial elements eventually undergo replacement by collagen and there is a contraction of the endoneurial area. Jopling and McDougal (1988) stress that fibrosis of nerves is inevitable where patients have not sought treatment until the disease has reached an advanced stage. Fibrosis is likely to be a gradual development. It reflects an advanced stage of disease with heavily bacillated nerves and may become apparent after treatment. This is explained by the observation that fibrosis is a reaction to granular (dead) bacilli. This conclusion was made on the basis that fibrosis has not been described during the early stages of disease when solid staining bacilli may be identified.

A further feature of late stage lepromatous leprosy is the thickening of peripheral nerves. Nerve thickening found in tuberculoid or borderline leprosy subsides with treatment. By contrast, nerve thickening may be preceded by treatment for lepromatous leprosy and emphasises the urgency for early diagnosis.

2.1.4.3 Neuropathy in borderline (dimorphous) leprosy (BB)

This manifestation of leprosy occurs in those who demonstrate a state of resistance between those of the polar forms. The neurological syndromes are based on the interaction of host resistance with tissue temperature. An important feature of borderline leprosy is the frequency and extent of nerve damage. Prolonged periods of polyneuritis presenting as thickened nerves, with or without skin anaesthesia or paralysis may precede the onset of skin lesions (Jopling and McDougal 1988).

Whilst nerve damage in borderline leprosy is essentially limited to the same sites as those common in lepromatous leprosy, the potential for uncharacteristic neurological defects is greater. It is suggested that cases of borderline leprosy demonstrate the greatest potential for catastrophic peripheral nerve damage. This is explained by a dual effect. There is a degree of resistance resulting in a prompt and radical response to detected bacilli, reflecting tuberculoid type nerve damage. Furthermore, an inadequate tissue response ensures that a haematogenous spread of disease is not prevented. As a result wide spread nerve damage is demonstrated early in the disease. Where a borderline case demonstrates a tendency to fall closer to the tuberculoid pole, the patient may present with a greater number but less demarcated lesions than in tuberculoid leprosy. Lesions are insensitive and anaesthesia is coterminous with the lesion. The lesions may or may not be associated with mixed nerves coursing beneath them. Paralysis and sensory loss are always asymmetrical (Sabin and Swift 1984).

Borderline cases lying at the mid point of the spectrum present with large insensitive lesions that may coalesce. Although the lesions are insensitive the anaesthesia may not extend to the periphery. Sabin and Swift (1984) suggest that the spread and coalition of lesions appears not to be affected by temperature gradients, and large

areas of insensitivity may occur. Involvement is asymmetrical and indicates intracutaneous nerve dysfunction as the borders of insensitivity do not conform to dermatomes.

In a low resistance borderline case there will be numerous lesions, symmetrically distributed. Areas of insensitivity may exceed the borders of lesions and temperature linked patterns of sensory loss become apparent. However, the spread of involvement is less diffuse than in lepromatous leprosy and is not as symmetrical.

Reactions in borderline leprosy

Borderline leprosy is characterised by instability. The status of the patient in the spectrum of resistance may alter. Factors effecting alteration that results in a shift toward low resistance lepromatous disease (i.e. downgrading) include general debilitation, prolonged administration of steroids, lymphoma or leukaemia. Acute nerve trunk lesions are not seen as a result of downgrading reactions. Alternatively an "upgrading" or reversal reaction may result from appropriate antimicrobial treatment that shifts the patient to a high resistance status. Peripheral nerves involved in reaction are the same nerves as those affected by the insidious yet massive proliferation of bacilli. With a reversal in immunological reaction to bacilli the subsequent effect on neural tissue can be devastating. Sections of nerve may become intensely painful and paralysis may be rapid in onset and total in effect. With subsidence of the acute stage the involved nerve trunks demonstrate epithelioid granuloma and fibrosis replacing endoneurial elements. The effects of reaction, if treated appropriately, may be minimised (Bjune G. 1983, Rose and Waters 1991 Becx-Bleumink 1992).

2.1.4.4 Neuropathy in pure neural leprosy

Probably because it is the least well understood presentation of leprosy, pure neural leprosy is frequently undiagnosed. It is often mistaken for other forms of hypertrophic neuropathy because of the enlargement of nerves in the absence of skin lesions. Jopling and McDougal stress the importance of nerve biopsies to establish a diagnosis. The palpably thickened nerve does contain excessive amounts of

diagnosis. The palpably thickened nerve does contain excessive amounts of intraneural collagen but pathologic diagnosis is based on the demonstration of acid fast bacilli in the nerve.

Sabin and Swift (1984) suggest that it is a manifestation of dimorphous leprosy. Jopling and McDougal (1988) cite other workers describing a variety of biopsy results correlated with lepromin tests that suggest a wider range of involvement. They report findings of pure neural tuberculoid leprosy as well as pure neural borderline lepromatous leprosy. However, they do agree that pure neural borderline tuberculoid leprosy is the most common finding.

2.1.5 A RATIONALE FOR SENSIBILITY TESTING

In order that the body can protect itself and maintain homeostasis it is essential that it has a sensory reference point which relates to normality. This "somesthesis" has been described by Lim as a sense of feelinglessness. Deviations in mechanical, thermal or chemical changes disturb this state so that an organism recognises a deviation from the somesthetic state and acts to restore what Lim (1968) has described as "sensory Nirvana" or comfort. It is little wonder therefore that the breach in afferent feed back, as a sequela of leprosy can be so catastrophic.

Pain is an indication of discomfort beyond the boundaries wherein semiconscious adaptations can restore us to comfort. It contributes to our somesthetic image which is maintained by the three modalities of mechanosensation, thermosensation and chemosensation. These modalities submit information relating respectively to touch and pressure, temperature and ache (Lim 1968).

Although the degree of pain perceived is dependent on psychosomatic factors the evocation of pain is a relative to the intensity of an injury stimulus. A supramaximal stimulus occurs when all receptors and axons in the vicinity of the injury are stimulated, regardless of their type. Injury stimuli are supramaximal and involve all afferents, but the distribution of chemoreceptors (normally in tissues deep to the skin)

suggests that their contribution may be incidental (Lim 1968). Lim postulated that chemoreceptors are stimulated by the chemical changes associated with inflammation and are, therefore, indicators of the consequence of injury. In ischaemic conditions local acidosis serves to sensitise chemoreceptors. Lim cites evidence indicating that acidosis inhibits kininase thereby augmenting the stimulation of the chemoreceptors by bradykinin. An interesting aspect of Lim's postulation is that pain, induced by mechanical stimulation of an inflamed area, may result from central disinhibition rather than an alteration in the properties of the chemoreceptors. Support for this hypothesis requires that disinhibition results from augmented impulses from mechanoreceptors and thermoreceptors. Total cutaneous mechano and thermal sensory loss of the plantar aspect of the foot is common in leprosy. However it is not uncommon to find subjects with recorded sensory loss complaining of acute pain associated with deep seated inflammation. Lim's hypothesis supports the suggestion that neuropathy in leprosy is primarily intracutaneous. Sabin and Swift (1984) identified a disparity in reports of sensory loss. They suggested that this may have been due to testers not recognising the different neuropathic effects of paucibacillary leprosy and multibacillary leprosy. The former may affect individual dermatomes, thereby demonstrating clearly defined areas of sensory loss. Multibacillary leprosy may exhibit diffuse intracutaneous loss without demonstrating major nerve trunk involvement.

Mechanoreception.

Cauna (1968) found that Pacinian corpuscles are the only receptors in human tissue supplied by an undivided myelinated axon (other superficial receptors have a shared nerve supply; thick myelinated sensory axons ramify to continue as branches to a wide extent of skin area). These structures are sensitive to vibration. Their morphology is such that those found on the sole of the foot continue to be sensitive even when the full weight of the body compresses them. Although detecting mechanical vibrations over a frequency range of 70-1000 Hz they do not respond to frequencies of lower than 50 Hz. This implies that they cannot register steadily maintained deformation of the skin. Their activity is also limited to a steady temperature state.

Meisener's corpuscles, found only in the papillary ridges associated with the epidermis of glabrous skin, respond to displacement of the skin. With these corpuscles discharging impulses in a frequency range of vibratory stimulus between 10 to 200 Hz a clear synergism is demonstrated with Pacinian corpuscles. Meisener's and Pacinian corpuscles represent a range of rapid firing receptors of which they are considered to be the most significant (Iggo 1982).

The ability to register sustained pressure of indentation is due to the effects of slow adapting mechano receptors. Of greatest significance here are the Ruffini endings and Merkel cells as they provide information relating to long term changes in the mechanical properties of the skin (Jorgenson and Bosjern-Moller 1991). Situated in the deep aspects of epidermal pegs which project into the corium, Merkel cells float in loose connective tissue. They are stimulated by deformation of the epidermis but are protected from noxious stimuli by virtue of their depth. Merkel cells are usually silent in the absence of a sustained mechanical stimulus. The Ruffini endings, by contrast, discharge regular streams of impulses when the skin is stretched. Ruffini endings are distributed less superficially than Meisener's corpuscles and have been described as deep as the capsules of diarthrodial joints (Iggo 1982).

In a comprehensive study of cutaneous sensation, Iggo (1982) records that there may be more than fifteen distinct types of cutaneous receptors. He presents histological and physiological details relating to receptors from the three main groups. Iggo presented evidence demonstrating that there are clearly defined functions attributed to individual types of mechano receptor. However, in discussing peripheral specificity, Iggo states that a majority of cutaneous receptors will respond to a wide variety of different stimuli and suggests that they are, at a gross level, non-specific.

Nociception.

There is general agreement in the studies of Lim (1968) and Iggo (1982) that, regardless of the nature of an injury stimulus, if it is sufficiently intense, it will excite mechano and thermo receptors. However these systems have been recorded as reaching maximal activity by innocuous stimuli. It is suggested, therefore, that

mechano and thermo receptors cannot mediate pain per se. It is proposed that it is the encapsulated free nerve endings that signal high intensities of pain. Free nerve endings are widely distributed. They are described as being found in the dermal papillae and the layers of the corium. Cauna (1968) cited evidence demonstrating that intraepidermal nerve endings extend with the epidermis to undergo atrophy before being lost with desquamation of keratinocytes. Following methods to analyse nociception, two basic types of receptor have been described. Mechanical nociceptors respond to actions that result in squeezing, crushing or pricking the skin. Mechano-thermal nociceptors, as the term implies, respond to severe mechanical or thermal induced stress. Conducting at velocities of 50ms^{-1} , mechanical nociceptors are capable of signalling rapid warnings associated with the earliest noxious stimuli. As opposed to "first pain", signalled by mechanical nociceptors, unmyelinated thermomechanical nociceptors conduct at a velocity of 10ms^{-1} . This activity signals a sustained response referred to as "second pain".

2.1.6 SENSIBILITY TESTING: METHODOLOGICAL ISSUES

"Sensation is defined as an impression conveyed by an afferent nerve to the sensorium whereas sensibility is susceptibility of feeling; ability to feel or perceive."
(Callahan 1984)

General considerations

Callahan (1984) describes the rationale supporting three categories of sensibility test. Objective tests are those that require only the passive co-operation of subjects. These are free from patient related variables of attitude, concentration, suggestibility and anxiety. Objective tests include tests of the sudomotor system and nerve conduction studies. Functional tests assess the quality of sensibility and indicate the status of tactile awareness. Tests, including two point discrimination, demonstrate the status of fine discriminative sensibility which allows active exploration and manipulation, independent of visual or vestibular apparatus. Modality tests do not require the high level of sensory processing that functional tests demand. Termed "academic" tests they are distinguished from "functional" because they seek to identify the status of

modalities at a gross level without assessing the ability to relate the stimulus to function.

Sensibility tests are highly subjective and where sensitive information is required extraneous variables must be identified and controlled. Callahan (1984) discussed some of the recognised variables and suggested control measures. She advised that testers should be aware of the distraction of environmental noise. Interference includes the cue effect of sound from testing instruments. Patient-related psychological variables are a complex issue. The examiner should be aware of the attitude of the subject toward the test procedure and be vigilant for the effects of anxiety or bravado. Patient-related variables have been identified as presenting the greatest potential for confounding results. Instrument-related variables should be controlled by calibration, whilst methods of testing should satisfy criteria for external and internal validity by demonstrating repeatability and intra/inter-rater reliability.

Modality testing.

Reviewing the findings of other observers Sabin and Swift (1984) recorded a general disagreement on the sequential loss of sensory modalities. Loss of any one modality before another, may not definitively indicate progression of disease. Conjectures made hereafter are subject to this limitation.

2.1.6.1 Pain perception

Pain perception is weighted by subjectivity and subject understanding of the required sensory information. In Sabin and Swift's experience, subjects with Leprosy were able to differentiate sharp from blunt when tested using a pin but were unable to equate the sensation with pain. Bickerstaff and Spillane (1989) support the use of the pin to discern pain. They recommend that the pin should be applied initially to an area of skin not affected by sensory loss. In this manner the patient is familiarised with the sensation under detection and should respond accordingly when the test is applied to the foot. It should be recognised, however, that a variable effect may still be registered where plantar skin thickness presents a barrier effect (Callahan 1984).

Opinions on the clinical efficacy of the pin prick vary. A detailed graded response is advocated by Sunderland (1978) and earlier by Seddon (1975). Callahan (1984) cites others as rejecting the test following ethical considerations (i.e. discomfort to the subject) or claims that it does not correlate with "functional sensibility". The term functional in this context denotes sufficient return of sensibility to enable a stimulated area to respond to a perceived stimulus. Tactile gnosis, by way of example, involves sensibility that enables man to perceive the foot's movement against the ground and the character of the weight bearing surface. To this end, the ability to register pressure coupled with withdrawal and postural reflexes are essential for self protection (Bosjen-Moller and Jorgensen 1982). The ILEP guidelines to nerve function testing recommend that only pressure stimulus should be tested and that this can be accomplished by using a ball point pen. They suggest that the skin should be indented to a depth of between 1 to 2 mm (ILEP 1994). Callahan (1984), however, suggested that where there are other indications of sensory loss, pain may "function" as the principal protective mechanism. She suggests therefore that the status of the modality must be ascertained.

Bickerstaff and Spillane (1989) recommend the use of the pin for testing pain stimulus. They state that in clinical practice it is as efficient as other methods that have been developed to produce graduated stimuli.

2.1.6.2 Vibration perception

The integrity of the foot is dependent on safety information relating to current conditions of the substratum. The high density of Vater-Pacini corpuscles in the subcutaneous fat chambers provide an acute sense of deep pressure and vibration associated with high frequency shock and tissue displacement. Meisener's corpuscles, however, register low frequency shock (Bosjen-Moller and Jorgensen 1982). Cauna identified Ruffini endings, as deep as the capsules of diarthrodial joints. This may explain Fox and Klemperer's earlier postulation that vibration sensibility may include a "deep" component derived from the proprioceptive sense organs (Fox and Klemperer 1941, Cauna 1968). Clearly, instruments capable of stimulating these deeper

receptors are required to discern the competence of vibratory perception.

Bloom *et al.* (1984) assessed vibratory thresholds using a Biesthesiometer (Bio-Medical Instrument Company). Applying the instrument probe to the medial malleolus and the base of the hallux, amplitude of vibration was increased until subjects registered perception of the stimulus. This method was adopted by Klennerman *et al.* (1990) in a study that sought to investigate whether there was a correlation between sensory loss and tarsal disintegration in leprosy.

Bickerstaff and Spillane (1989) advocate the use of a 128 HZ tuning fork to indicate loss of vibratory sensibility. They recommend the use of the tuning fork in clinical practice, under the proviso that careful explanation is given to subjects to avoid inappropriate responses. Following their study, Klennerman *et al.* (1990) also recommended that the 128Hz. tuning fork would be a suitable instrument for clinical use in developing countries. Although it does not contribute to objective analysis, the reliability of the method as indicating gross modality loss is confirmed in their study. The mean biesthesiometer threshold they recorded was 23.4 μ M (std.13.5, range 4.8 μ M - 50 μ M, n=22). Based on the findings of Fox and Klemperer (1941) a 128Hz tuning fork will deliver a stimulus corresponding to 2-4 μ M. All the subjects in the study of Klennerman *et al.* displayed thresholds over the 4 μ M level regarded as a criterion for sensory loss. However sensibility at one site may be different from the second site (Klennerman *et al.* used the mean threshold corresponding to both sites as the value for each foot in their investigation). Vibratory loss at both sites should therefore be confirmed and monitored as a degree of sensory function may be demonstrated as presenting an extraneous variable affecting ulcer resolution.

The subtle disparities of sequential loss probably become less relevant where multiple major nerve involvement has attenuated perception of vibration. Sabin and Swift (1984) suggest that position and vibration sensation are only impaired in "unusual or very advanced" cases of leprosy. Klennerman *et al.* (1990) defined criteria for classification of loss of sensation as the inability to perceive 5.07 hair (Semmes Weinstein monofilament), a vibrometry value greater than 4 (Biesthesiometer Bio-

Weinstein monofilament), a vibrometry value greater than 4 (Biothesiometer Bio-Medical Instrument Co.) or plantar ulceration.

2.1.6.3 Pressure perception

The sensory neurophysiology of the palmer surface has received greater coverage in the literature than the plantar surface of the foot. Many advances in the objective analysis of sensibility are the result of the inventiveness of clinicians seeking to advance knowledge of the sensory functions of the hand.

Shortly before the turn of the century Von Frey (cited by Bell 1984) developed an objective method of pressure testing. He pioneered the use of monofilaments and strove to produce repeatable results by developing a consistent tip on the end of the filaments he used. His rationale was that a consistent tip would allow constancy in the size of the tip/skin interface during bending of the filament. With a constant tip surface, pressures produced would vary only according to the force applied.

Semmes and Weinstein developed Von Frey's original initiative (Weinstein 1993). They developed the Semmes Weinstein Pressure Aesthesiometer (Research Designs Inc., Houston). The instrument comprises a set of 20 graded nylon monofilament probes. Each probe is attached to an individual polymethylmethacrylate rod. The 20 probes are numbered from 1.65 to 6.65. Each number represents a value that is the logarithm of 10 times the force in milligrams required to bend the monofilament. The logic is that when applied perpendicular to the skin, the lightest probe will bend when a force of .0045 gms is applied whilst the 6.65 probe will bend with a force of 448 gms. (Callahan 1984).

Since the introduction of the Semmes Weinstein Pressure Aesthesiometer, the method has been used in studies of nerve function in leprosy (Berger 1987, Jennekens and Jennekens-Schinkel 1992, Bell-Krotoski 1992, Van Brakel *et al.* 1994). Birke and Simms (1986) used Semmes Weinstein filaments to identify a level of protective sensation on the plantar surface of the feet of leprosy patients. They concluded that

the 5.07 filament (10gms) was a suitable instrument for screening patients at risk of plantar ulceration. The 5.07 filament is now commonly used as an objective indicator of nerve loss where studies are conducted in Indian leprosy institutions.

The Semmes Weinstein Aesthesiometer is not without criticism. Bell (1984) identified problems relating to the unequal increment in forces. On consideration, she found the interpretation scales disproportionate and confusing. Adjustments between filaments was found to demonstrate an increment of 18.5mg in one instance compared to an increment of 165.5 gm. in another. Dellon *et al.* (1993) investigated the reliability of the Semmes Weinstein Aesthesiometer which they asserted had been used extensively over a thirty year period as the only instrument to determine cutaneous pressure thresholds. Examining the intention that the markings represent a logarithmic function to the base 10 of the force in milligrams, they identified the confusion as stated by Bell. They elucidated the situation by demonstrating that the difference in threshold between 2.83 and 4.93 would be a 100 fold difference and not a difference of 2. Dellon *et al.* found that by calculating what the force in milligrams should be from the filament markings they arrived at values different from those listed in the manufacturer's table. Examining the issue further they consulted the original monograph submitted by Semmes and Weinstein. They found that the original definition of the markings was the log to the base 10 of the force in *tenths* of milligrams whereas they report the manufacturer's tables list the force in *grams*, not tenths of milligrams.

Their conclusion was that the Aesthesiometer markings should only be used to "represent" a pressure which could subsequently be treated numerically for statistical purposes. If this criticism is valid there is little justification for choosing the method in preference to the simple ball point pen method.

Callahan (1984) has described light touch and deep pressure sensitivity as representing "two ends of a continuum of cutaneous sensitivity". Discussing the use of non graded instruments she suggested the pressure sensibility has been tested using diverse methods including the blunt end of a pencil and the finger tip of an examiner.

An obvious limitation in the use of non graded technique is that an objective analysis illustrating intervals on the continuum between light touch and deep pressure cannot be recorded. Only an indication whether the stimulus could be felt or not can be obtained. Callahan however suggests that accepting these limitations, non graded instrumentation can provide valid information if used by a skilled examiner. She recommended that a stimulus can be applied with either a moving or constant touch. Stimulus should be of one second duration and the subject should be required only to indicate perception verbally without being required to indicate the location of the stimulus. Two nonsuccessive stimuli should be applied to each site under examination and responses should be interpreted in the following manner:

two correct responses of two trials = intact

one correct responses of two trials = diminished

no correct responses of two trials = absent

Callahan's comments were made with direct reference to the hand. Although there are differences in the sensibilities of the two glaborous surfaces similarities have been reported. Robbins *et al.* (1993) have suggested that the sensory thresholds in the foot should be considered to be twice that found in the hand. Callahan's recommendations are similar to those suggested by Watson (1989) in her manual for leprosy field workers. She suggests that subjects should point to the site being tested. If a distance greater than 2cm from the point of application is indicated, it should be considered that the modality has been lost.

2.1.7 A RATIONALE FOR ULCER ASSESSMENT

The ulcer assessment protocol included examination of the morphology and dimensions of ulcers. To demonstrate the rationale supporting the protocol a review of ulcer pathogenesis and physiological responses to tissue trauma are presented.

2.1.7.1 The stress / strain relationship

The relationship of stress and strain is a fundamental consideration describing the mechanical properties of soft tissue. Strain is an expression of deformation that occurs at a point in a structure under loading. Normal strain is the ratio of deformation to original length whilst shear strain is the representation of angular deformation. Although frequently expressed as a percentage, being a ratio, strain is dimensionless. Rodgers and Cavanagh (1984) cited Young's modulus of elasticity to demonstrate the ratio of stress to strain. However, since it has been demonstrated that biological soft tissues do not exhibit the linear stress strain relationship displayed in some engineering materials, the expression "apparent" modulus of elasticity is more accurate (Thompson 1988). The apparent modulus of elasticity is defined as stress divided by strain and has the units of stress (i.e. Pa or $\text{N}\backslash\text{cm}^2$). Similarly, the term shear modulus, describing the effect of shear stress divided by the resultant angle of deformation, differentiates the properties of resistance exhibited between normal stress and shear stress.

When a measured stress is applied to soft tissues and strain is time measured simultaneously, a stress-strain curve for soft tissue may be plotted. This stress-strain curve demonstrates that soft tissues are non linear and viscoelastic. Gibson *et al.* (1976) discussed the lax phase of tissue deformability under tension. They focused on the limit strain which is the point at which an increasing application of force tends to produce a linear stress strain relationship indicating a stiffer response of tissue to stress. A significant observation was that the magnitude of the limit strain varied, not only according to the site from which excised skin was taken but also from orientation of the skin being tested. Local orientation and anisotropy may explain

peculiar tendencies in ulcer healing.

The easy initial deformation of skin under low stress is attributed to the stretching of elastin fibres and the alignment of collagen. Following a critical preload, tissue becomes progressively stiffer requiring greater stress to effect smaller deformation. This effect is due to the poor compliance of the relatively nondistensible collagen fibres. If the load is relaxed during the initial period of strain where predominantly elastin fibres are affected, the unloading curve is almost identical to the loading curve. This is because there is a low modulus of elasticity due to high concentration of elastin. The quality of soft tissue behaviour demonstrated during this phase of deformation is mouldability. Mouldability protects the foot by increasing the load bearing area thereby reducing foci of stress. If however the load persists through the phase where increasing force elicits reduced deformation, the unloading curve does not follow the loading curve.

Hysteresis, displayed by soft tissue, is attributed to the viscous elements in which some energy is stored and dissipated. The viscous modulus of soft tissue increases with load thus demonstrating soft tissue adaptation to provide shock absorption, stability and mouldability.

Fatigue describes the resistance to normal or shear stress displayed by any structure subjected to stress. As a general principle, fatigue failure is avoided as the fatigue period of soft tissue is such that it allows sufficient time for self repair. Where strain has been excessive there is a degree of soft tissue relaxation on relief from load. This recovery may however be incomplete. If the number of load cycles, or the magnitude of stress is such that tissue recovery periods exceed the fatigue period, the tissue will experience fatigue failure and breakdown.

The major mechanical characteristics of soft tissue are demonstrated using the analogous Kelvin Model (Thompson 1988). This model suggests that it is the viscoelasticity of soft tissues that determines adaptation to the nature of the weight bearing surface and accommodation of sudden variations in force. Viscoelasticity of

tissue is likened to the spring and dashpot combination of the Kelvin model (see Fig. 4). The compression of the spring and shock absorbent reaction of the dashpot decelerate the body and minimise peak stresses. Thompson (1988) applied the relationship, between the impedance of a Kelvin element and an increase in frequency, to human soft tissue. He suggested that there is an initial linear relationship between a drop in impedance and an increase in frequency governed by the elasticity of the system. Decrease in impedance is restricted by the viscous element. The Kelvin hypothesis is substantiated by others who have demonstrated that the elastic and viscous moduli of human soft tissue are quantifiable using impedance testing.

The Kelvin model further reflects soft tissue function in the storage and dissipation of energy. When compressed, energy is stored within the elastic elements (the spring) until it is unloaded with decompression. During rapid decompression the viscous elements of soft tissue (the dashpot) permits shock absorbency converting mechanical energy into thermal energy. Local heating is controlled by the dissipation of energy through the vascular system. An alternative dissipation of mechanical energy is the destruction of solid structures.

2.1.7.2 The role of soft tissue structures

The elaborate anatomy of the forefoot appears to leave the forefoot less well equipped to reduce a greater magnitude of force than the heel.

Connecting the deep side of the plantar aponeurosis with the flexor sheaths, plantar plate of the metatarsophalangeal joints and proximal phalanges are sagittal septa. These septa contribute toward containing a cushion of fat enclosed by retinacula that extend from the dermis to the flexor sheaths. These more robust structures over the metatarsal heads are interspersed with fat bodies protecting the digital nerves and vessels. The anterior displacement of these fat bodies is prevented by transverse lamellae in the web of the foot.

The efficiency of plantar structures was tested by Jorgenson and Bosjen-Moller

(1989). They defined shock absorbency as a ratio of peak force reduction and of energy loss at impact. They compared human heel pads with samples of ethylene vinyl acetate and sorbothane (a viscoelastic insert material) and found that the heel pad shock absorption rate was 1.1 times that for E.V.A. and 2.1 times that for sorbothane. When they studied collision forces they recorded that energy return, after impact, was approximately 30% without and 20% with normal hydrostatic pressure in the veins (Jorgenson and Bosjen-Moller 1991). On the strength of these findings they concluded that the heel is critically dampened for load and impact speeds by squeezing the blood into the superficial veins from the vascular bed. In this manner some of the energy is dissipated for venous return against gravity rather than being dissipated as heat. Specialised fat, containing up to 25% more unsaturated fatty acid making it, by inference, less viscous than other adipose tissue is contained within chambers separated by septa. These structures are organised in such a fashion that a superficial layer of microchambers, in a highly vascularised bed, overlies a deep layer of macrochambers. The two layers are separated by ligamentous structures attached to the periosteum of the calcaneal tubercle by a system of U shaped septa that prevent overflow of fat between chambers (Jorgenson and Bosjen-Moller 1991).

Jahhs *et al.* (1992) observed that injected India ink did not spread into the fat pad of cadaver specimens. It extended only along the needle track to the surface of the calcaneus and then beneath the long plantar ligament and intrinsic muscles. Following this observation Jahhs *et al.* examined specimen heel pads with a scanning electron microscope. They described the fat pad as having a reticulated configuration with apposite adjacent cell walls denying intercellular spaces. Analysis of septa construction revealed "kinked fibroelastic bundles" of collagen and elastin. Coronal macrosections of heel pads were described as demonstrating greater concentrations of septa on the lateral aspect of the heel compared with the medial side. These macrosections displayed thicker, more numerous septa posteriorly compared with sparse anterior septa containing smaller fat globules. In another study an interesting observation, that was not commented on, was the predisposition for medial loading (Jahhs *et al.* 1992). Their methodology dictated that subjects would demonstrate medial loading due to the position adopted. Support on one limb with the foot in

dorsiflexion would cause the subtalar joint to pronate and therefore result in medial loading. The implications for a structure designed to address greater stress on the lateral side are significant if medial loading is prolonged through the contact period of stance. The period of loading may have been the factor responsible for the painful heel syndrome complained of by some of their subjects who did not demonstrate significant heel pad structural differences.

In the same study a clear description of the function of fat pad structures was described. It was suggested that the internal reinforcement structures of the septae inhibit bulging. These structures were described as elastic transverse and diagonal fibres that connect septal walls. A greater number of small compartments present larger numbers of walls to be stressed. Smaller structures offer greater resistance to compressibility (tension is an expression of radius x pressure). Structure size, coupled with the internal reinforcement factor, demonstrates how the mechanical properties of the fibres and structure of septa walls may permit increased resistance to deformation.

Jahss *et al.* (1992) investigated the load bearing ability of the heel pad. A comparison was made between "normal" pads, described as being "moderately firm", "floppy" pads indicated by a pad through which the calcaneus could be palpated, and "atrophic heels". The latter demonstrated a thin pad through which the calcaneus was prominent. They concluded that a thicker heel pad resulted in lower peak stresses distributed over larger areas. They also suggested that constraint of the heel can result in lower stress levels by limiting lateral or medial bulging. Jorgenson and Bojsen-Moller (1989) illustrated that when the large lateral expansion at heel strike was confined shock absorbency was increased. They recorded shock absorption variation of as much as 100% between heel pads. This may be explained by Kuhn's finding that heel pain was correlated with thinner irregular septa or ruptured septa with confluent chambers (Kuhn 1949). Jahss *et al.* (1992), presenting evidence provided by their India ink tests, refuted the suggestion that there could be degeneration of sufficient severity to permit interseptal fluid flow. Their histological studies, however, suggest that the septa may develop altered mechanical integrity. Jorgenson and Bosjen Moller (1989) found a 24% decrease in shock absorbency

where heel pads had been traumatised. Jahss *et al.* (1992) agree that the mechanical integrity of the fat pad was dependent on the closed cell structures of the septae. They described septae with a higher concentration of fragmented elastic fibres in the specimens drawn from dysvascular feet. Although there appears to be a relationship between fragmented septae and atrophy of fat cells, it is unclear whether either factor can be implicated as the primary cause of fat pad degeneration. They suggest that a predisposing factor may be a compromised vascular supply or neuronal dysfunction.

Jahss *et al.* (1992) recorded that the fat pad was abundantly innervated with free nerve endings. They suggest that these findings had not been described previously. Vater Pacini corpuscles were identified in the superficial and deep layers of the heel fat pad. Vater Pacini corpuscles, though deep and less numerous than free nerve endings in the fat pad were absent in the dermis. Free nerve endings were numerous (particularly in the heel pad) and although usually associated with adjacent capillaries, many were isolated within the fat. Jahss *et al.* have recorded observations that fat pad atrophy accompanies neuropathies related to diabetes and alcoholism. They present interesting anecdotal evidence of the atrophy of sensate free flaps after reconstructive surgery. It is suggested, tentatively, that neuronal supply may therefore exert a trophic influence on the fat pads of the foot.

The integrity of the foot is dependent on safety information relating to current conditions of the substratum. The high density of Vater-Pacini corpuscles in the subcutaneous fat chambers provide an acute sense of deep pressure and vibration associated with high frequency shock and tissue displacement. It is postulated that the Meiseners corpuscles register low frequency shock (Jorgenson and Bosjen-Moller 1991). The dual effect of these modalities is that the foot's movement against the ground and the character of the weight bearing surface may be perceived. The ability to register pressure coupled with withdrawal and postural reflexes are essential for self protection.

2.1.7.3 Ulceration

Brand (1976) did not completely dismiss the possibility that there may be a trophic element affecting tissue breakdown in insensitive feet. The nature of such an effect, if it is a relevant factor, is not understood. Brand therefore preferred to concentrate his investigations on the mechanical influences that cause tissue breakdown. He identified three distinct etiological factors which he recommended as topics for deeper investigation:

Pressure ischaemia

Sudden injury

Repetitive stress.

Pressure ischaemia

Pressure ulceration is the result of relentless pressure of between 50- 200 g/cm² being sustained for several hours, or of greater levels of pressure for relatively shorter periods (Brand 1976). Brand expressed doubt that pressure may cause any direct damage to cells. Cellular degeneration is not due to mechanical disruption but to deprivation caused by attenuation of the supply of nutrients. Tissue is isolated, not only from blood but also from tissue fluid through which nutrients diffuse. Branemark (1976) explored phenomena relating to the behaviour of blood and circulatory malfunction as a result of compression. The most striking feature of his investigation was that after skin had been occluded for as long as 7 hours, circulation was re-established with minimal damage to the microvascular system. However, the distension of the walls of microvessels as a response to vascular pressure was established.

The complex, interrelated sequence of vascular response, cellular reaction and involvement of chemical mediators contributes toward a breakdown of the balance between extra and intravascular environments. Localised disorganisation exacerbates microvascular catastrophe and a spiralling degeneration of tissue is perpetuated.

Brand (1988) suggested that pressure ischaemia per se is not a common cause of

ulceration in insensate feet. He suggested that the incidence of such is probably limited to subjects wearing tight ill-fitting footwear. Several hours of low grade pressure in non-ambulant patients (e.g. those in bed through infirmity) may cause pressure ulceration, but these effects are not generally experienced in ambulant populations.

Sudden injury

A further cause of ulceration is an incident whereby unguarded tissue is exposed to a sudden and intense level of direct or shear stress. The level of stress required to elicit tissue disruption is dependent on the anatomical location at which the force is applied, the integrity and structure of connective tissue and skeletal support. The nature of force applied is a further variable. However, whether the stress applied is compressive, tensile or shear it is suggested that the magnitude of force required to cause direct disruption may be as much as one thousand times greater than that required to cause ischaemia (Brand 1988).

Repetitive stress

Most of the current understanding of the mechanics of ulceration is due to the contributions of Brand (1975, 1976, 1989, 1991) who found support for the hypothesis that tissue necrosis could result from repetitive moderate stress. Brand's investigation was a significant contribution to knowledge of the pathology of ulceration. He recorded that subjects regularly ulcerated at areas subjected to pressures of 1-5 kg/cm². Whilst such pressures were 10 to 20 times greater than the pressure required to elicit decubitous ulceration, they were considerably less than that required to cause direct disruption. Finding single applications of force exceeding 10kg/cm² tolerable, Brand postulated that repetitive low pressure may be a more significant factor.

Using a walking simulator, he and his colleagues delivered very low grade repetitive mechanical stress to the foot pads of rats. They recorded that there was an increased surface temperature relative to the number of repetitions applied to tissue. This was, in itself, not a remarkable finding. However, it was found that rats which were

subjected to high numbers of repetitions on the first application demonstrated higher temperatures as a response to a smaller number of repetitions a week later. Studies of van der Leun *et al.* (cited by Brand) demonstrated that adherence of the epidermis to the dermis was reduced by an increase in temperature. The viscous bonding of the dermal-epidermal interface is a major factor stabilising the structure of the skin. Establishing a time temperature relationship implication in the breakdown of the viscous bonding was, therefore, a significant development.

Pressures of the same magnitude were applied at 10,000 repetitions daily for 10 days. Histological examination revealed that on the second day there was evidence of inflammation and oedema. By the third day there was evidence of epidermal cell separation and a suggestion of subcutital necrosis. After 1 week it was found that necrosis was a common feature and although the keratin layer remained intact, in some cases there was a loss of epithelial continuity. Adjacent to the area of breakdown there was a noticeable hypertrophication of epithelium. After ten days frank clinical ulceration was described. Areas of cellular necrosis were surrounded by hypertrophic skin with an excessive depth of keratin.

By contrast, the same pressures applied at 8,000 repetitions a day for five day periods were repeated until each rat had been subjected to stress for twenty-eight days. Under these conditions results suggesting adaptation were recorded. Epithelial discontinuity and necrosis with oedema and adjacent epithelial hypertrophication were recorded after seventeen days. However by the twenty fourth day there was a reduction in necrosis with an increase in hypertrophication of all epithelial elements.

Considering these findings Brand (1976) postulated that the changes found may be the result of cellular autolysis. The repetitive nature of the mechanical stress leads to an accumulation of inflammatory cells from which greater concentrations of lytic enzymes are continually released. In later publications Brand (1988, 1991) reiterated that unremitting repetitive loads may be more deleterious than high peak pressures. He considered that the insensate foot was particularly vulnerable to insidious trauma of this nature. Micro trauma, with consequent cellular infiltration and haemorrhage,

results in cellular degeneration and necrosis. Oedema, developed as a consequence of inflammation, concentrates weight bearing forces on itself thus multiplying the potential for ulceration by developing exacerbating an ischaemic environment (Livingstone 1992). These issues are detailed below.

2.1.7.4 The Physiological Response

The physiological response to wound healing follows a recognised sequential pattern regardless of whether the cause is surgical or indolent (Westaby 1982, Zederfeldt *et al.* 1986, Kloth and Miller 1990, Thomas 1990). The biochemical and cellular responses, demonstrated as inflammation, proliferation and maturation demonstrate continuous process that aims to restore continuity and tissue strength. However, the precision with which events within the process may be predicted becomes untenable where wounding is the manifestation of insidious repetitive insult to tissue. The overlapping phases of inflammation, epithelialisation, contraction and connective tissue formation are continuously disrupted and the process of resolution or organisation is confounded by the effects of chronic inflammation. Westaby (1982) related prolonged inflammatory response with a delay in tissue regeneration and consequent retarded development of tissue tensile strength. Retardation of healing is ascribed to an over abundance of polymorphonucleocytes responding to chemotactic influences. Whilst monocyte activity is enhanced by a hypoxic environment it is the massive accumulation of neutrophils, basophils and eosinophils that contributes to a relative nutrient deficit. This is explained by the competitive nutritional demand created by the excessive numbers of highly active cells.

It has been suggested that there is an objective transition from acute to chronic inflammation. Kloth and Miller (1990) proposed that an acute inflammatory phase of two weeks duration is followed by a two week sub acute phase. Inflammation that persists beyond this period becomes chronic. It is differentiated from acute inflammation by being devoid of the cardinal signs of inflammation recorded classically as "*Rubour et tumor cum calore at dolore*" (attributed to Celsus, 1st. century A.D.). In a litany that includes infection, unresolved acute inflammation and

foreign body irritation, Kloth and Miller (1990) implicated repeated micro trauma as a factor promoting chronic inflammation.

In her study, Wall (1979) suggested that ulceration could be considered to demonstrate three stages and the each stage displayed representative characteristics. The "active phase", she proposed, represents an inflammatory response, which Westabury later suggested demonstrates traumatic and destructive sub phases.

The active phase of ulceration

The leucocytic migration to a traumatised location results in the active debridement of devitalised tissue. The lysis of short lived neutrophils results in the release of proteolytic and collagenic enzymes which are active in the early solubilization of necrotic tissue. Autolytic wound debridement is enhanced by the activity of monocytes. Complementing their phagocytic activity is the monocytic production of collagenase and proteoglycan degrading enzymes. Associated with the increased migration of macrophages and plasma proteins, is the accumulation of transudate. The normally clear, straw coloured serous exudate displays discoloration and odour reflecting its altered status as a cellular aggregate. The viscous and purulent aggregate of cells and debris which drains from an opened wound is a sterile exudation. Within a week the cells and plasma constituents of the exudate cease to function and become incorporated into a necrotic coagulum. Necrotic tissue (slough) may remain relatively fluid or dehydrate to become a hard eschar. In the active phase of ulceration discharge is copious. The volume of exudate inhibits the consolidation of materials to form an eschar. Oedema and infection can contribute considerably to the amount of exudate expressed (Kloth and Miller 1990).

Unresolved disruptive forces perpetuate haemostatic mechanisms. The occlusion of microcirculation serves to exacerbate the anoxic necrosis of tissue. Where pressure is implicated as a precipitating factor, endothelial cells lining the microcirculation, become separated. Cruikshank (1976) discussed the effects of proteolytic enzymes on the structure and function of skin. It was observed that trypsin acts on the protein-polysaccharide bond between epidermis and dermis. Furthermore trypsin is described

as breaking down intercellular cement substance. A sequence of breakdown events is initiated by the destruction of the contact substance between the adjacent spot desmosomes. With the loss of desmosomal contact, tonofilament attachment is also disrupted. With dissolution of the intercellular desmosomal contact the tension under which the skin is held is lost. The resultant separation of junctional complexes allows contact between procoagulants of the blood and sub endothelial tissues, notably collagen, causing an aggregation of platelets. Platelet aggregation leads to vascular occlusion and further tissue necrosis (Barton 1976).

Wall (1979) has recorded that the pathological process during the destructive phase of ulceration causes the lesion to spread inwards thereby destroying subcutaneous tissue faster than the overlying skin. The "undermined edges" of active ulcers are a characteristic feature. Trypsinisation does not have any effect on the epidermis (Cruickshank 1976) which may explain why the dermis breaks down at a greater rate.

The indurated and punched out edges of chronic ulceration are the manifestation of the accumulation of collagen. Kloth and Miller (1990) explain that engorged macrophages unable to solubilize phagocytic material due to hypoxia, continue to proliferate in inflamed tissue. Monocytes effect a powerful chemotactic attraction causing an extensive accumulation of fibroblasts with the resultant production of excessive collagen. The production of collagen results not only in induration of the periphery of an ulcer but also serves to effect the relationship of the lesion to underlying structures. Recently formed and active ulcers have been described as exhibiting a mobile relationship with deeper tissues. The organisation of fibrous tissue associated with chronicity results in the lesion being "tied" to deeper structures thereby reducing its mobility.

The proliferative phase

1. Granulation

A primary indication of ulcer resolution is the appearance of granulation tissue at the base of an ulcer. Daly (1990) suggested that the geometric structure of the wound and "various biologically active substances" are significant factors determining wound

repair. However, the actual chemical and cellular substances that promote the proliferation of granulation have not yet been identified.

Granulation tissue has been described as a vascular and lymphatic system in a gel-like matrix, contained within a fibrous collagen network (Thomas 1990). The matrix is composed of hyaluronic acid and fibronectin with other salts and colloidal materials. The vascular network carries nutrients to macrophages and fibroblasts whilst the lymphatics prevent oedema. Granulation tissue is produced until the wound cavity is filled reducing the depth of the ulcer almost to the level of the surrounding skin.

2. *Re-Epithelialization*

Thomas (1990) suggested that the spread of granulation to the level of the skin stimulates the activation of the epithelium which begins to proliferate over the wound. The re-establishment of an epidermis, as detailed by Daly (1990), includes the metamorphosis of epidermal and adnexal basal cells and epidermal cell migration.

The morphological changes exhibited by the epidermal cells are demonstrated, initially, as a flattening of the cell. This event is followed by the loss of desmosomal attachments and retraction of intracellular tonofilaments. The formation of actin filaments at the edge of the cell cytoplasm enables cells to migrate toward the area of cell deficit.

Daly (1990) discussed two hypothetical explanations of the migratory process. It may be that individual cells migrate no further than twice their length from original positions, then slide over previously implanted cells to become fixed. Successive cells continue to migrate over implanted cells until the wound is covered. Alternatively, epithelial cells may migrate across a surface drawing a "train" of cells. Migration may proceed until an opposite cell is reached.

Not only does the mode of transfer remain speculative, but stimulus for re-epithelialisation has not been established. Daly (1990) suggested that wounded tissue does not produce chalone, therefore the separated surfaces at a "free edge" would

not be subject to the inhibitory effect of chalone on biological events. This hypothesis may also explain the hyperkeratinization, frequently observed as callous, around the periphery of ulcers.

The basement membrane is established, extending from the periphery of the wound, once the epidermal cells have successfully traversed the wound. The final stages of re-epithelialisation are characterised by the resumption of cuboidal shape and the establishment of hemidesmosomal attachments between epidermal cells and the basement membrane.

The maturation or remodelling phase

An outline of events characterising this phase is described by Johnson (1984), and elsewhere by Jaber (1986). It includes the decline in concentration of fibroblasts and the complex reorientation of collagen fibres. A result is the eventual consolidation of scar tissue, which Johnson suggested displays a maximum strength of 20% less than that exhibited by intact skin.

The manner in which random fibres are organised into a system of optimally oriented fibres was detailed by Price (1990). The rapid process of synthesis and lysis of collagen in the early stages of healing is reversed during maturation such that the rate of lysis exceeds that of synthesis. The nature of biochemical bonding is also altered leading to the establishment of stronger molecular structures and links between collagen fibrils and ground substance. The weak bonding of collagen in developing scar allows for limited stretch as a response to stress. In contrast the denser and toughened mature scar is less resilient.

The realignment of collagen fibres is thought to be a response to pressure. When pressure is applied collagen releases "piezoelectric substances" (Price 1990). It is postulated that these stress generated voltages are responsible for the realignment and general maintenance of collagen. Price's perspective offers an important insight to wound healing. Her findings suggest that the strength of healed skin is determined by biomechanical stresses acting on healing time. The fragility of healing, resulting from

immobility, may be reduced by permitting careful movement of healing tissue.

2.1.7.5 Degenerative manifestations of ulceration

Regardless of classification, ulceration presents a challenge to homeostatic mechanisms that effect the restoration of tissue equilibrium. Viewed in this perspective the term "simple ulcers" seems inappropriate. However, the term is used to represent ulcers that involve only skin and subcutaneous tissue.

Mal perforans

Complicated ulcers extend to involve tendons, synovial sheaths, joint capsules and bone. Pyogenic infection of bone may result from the localisation of infection via a haematogenous route or from abscesses. Infection may lead to chronic osteomyelitis with multiple sinus formation. A more common causative factor contributing to involvement of deeper tissue is secondary infection of an uncomplicated ulcer. Enna (1988) explained that the spread of infection along tendon sheaths and into synovial joint capsules is facilitated by movement during walking. Sequestration, remodelling of bone and copious periosteal reaction are associated with pyogenic infection. In such cases, restoration of tissue stability is dependent on overcoming infection and the removal of necrotic bone and soft tissue. In the absence of compromising factors complicated ulcers proceed to heal by secondary intention.

Malignancy

It has been recorded that pyogenic sinus tracts associated with osteomyelitis may become complicated by the development of squamous epithelioma (Enna 1988, Brand 1991). Sane *et al.* (1988) suggested that another predisposing factor associated with malignant transformation is the chronic irritation of regenerating epithelium. It was postulated that chronic disturbance to regenerating epithelium stimulates an adaptive response displayed by the development of papillomatoses. Unresolved irritation leads to dysplastic change and the reduction in cellular differentiation leads to carcinoma.

2.1.8 ULCER ASSESSMENT: METHODOLOGICAL ISSUES

The objective measurement of ulceration is widely regarded as an essential indication of the efficacy of treatment (Wall 1979, Anthony and Barnes 1984, Sutton 1989, Kudin 1989, Johnson 1993). The measurement of reduction in size over time is a fundamental parameter for comparison as it indicates the extent to which intervention assists the homeostatic processes active in the restoration of tissue stability.

In her presentation of an approach to wound assessment Kudin (1989) made an oblique reference applauding the progress in objective evaluation from ordinal and interval observation to ratio observation. However she asserts that further data is required to monitor the healing process if advances are to be made in effective wound treatment. The major issue confronting the clinical recording of indications of physiological activity is the problem of subjectivity. This problem has not been well addressed in the literature although suggestions by Wall indicate that a model may be developed whereby fundamental features may be categorised using nominal data.

2.1.8.1 The measurement of dimensions

There are many references to measurement, technique and instrumentation in the literature. However a common flaw is that the question of validity has not been adequately addressed. Reliability and repeatability are not established and presentation is generally impoverished by the absence of statistical analysis.

Plassman and Jones (1992) recognised this deficiency in the literature. They suggest that the lack of objective information relating to the suitability of treatment methods is due to inappropriate measurement methods and devices.

They used a structured light scanning system which, they demonstrated, measured not only the area of ulceration but also the volume of an ulcer. This was achieved by calculating the difference between the virtual reconstruction of the former healthy skin, and the actual measured surface of an ulcer. By considering all relevant

parameters their system was demonstrated as presenting accuracy of measurement of $\pm 0.4\text{mm}$ in human tissue. The clinical application of their system is limited however as it can only be used under controlled light conditions. Their initiative represents the innovative use of technology but their method is limited. Cost and clinical application in field situations renders the approach untenable.

Johnson (1993) applies similar criticism to stereophotogrammetry. Exploring similar parameters to those chosen by Plassman and Jones (1992), a stereo camera is used to provide measurement of wound co-ordinates in three dimensional space. The accuracy of the system is not contested but Johnson suggested that the cost of the system is prohibitive for most units where it may be useful.

Photography may be used as an assessment tool where magnification, distance exposure and lighting can be standardised (Johnson 1993). Furthermore, the angle at which the photograph is taken must be established so that at subsequent assessments results will not be biased by a distortion of horizontal or vertical axes (Anthony and Barnes 1984). Criticism of photographic assessment extends to the observation that photography does not provide three dimensional information. As such some have suggested that photographic records cannot provide a valid comparison between subjects because visible surface areas may be an inadequate representation of actual size (Berg *et al.* 1990).

Hampton and Birke (1990) used X-ray film placed over an area of ulceration on to which the area of ulceration was traced. Photographic transparencies, or tracings of an ulcer may be measured using a planimeter. Whilst the accuracy of the planimeter may be established, the accuracy of tracing has been criticised. Anthony and Barnes (1984) cite Bulstrode *et al.* who reported error of 37% when calculating the circumference of wounds from tracings. Tracings are problematic because lesions are positioned on three dimensional anatomical surfaces, which are invariably rounded and irregular. A representation of an anatomical feature on a plane surface will inevitably present a distorted image.

Recognition of the irregular three dimensional nature of ulceration, and that the apparent surface area does not reflect the subcutaneous surface, convinced Berg *et al.* (1990) that ulcer volume was the most valid parameter by which changes in ulceration could be assessed. They were prompted to develop a simple, inexpensive, reproducible method of volume measurement. By applying a transparent adhesive film over the lesions, ulcers were filled with sterile saline solution. A needle placed at the highest point allowed air to escape. The volume of solution required to fill the wound is recorded. They acknowledge that their technique is limited in that it can not be applied to areas with little subcutaneous tissue. Whether it may provide a reliable means by which the volume of small lesions (.5mm x .5mm) may be recorded is doubtful. Berg *et al.* did not record whether ulcers should be debrided before or after the volume is calculated. Necrotic and atrophic tissue may exaggerate volume (as with a rim of callous circumscribing an ulcer) or detract from the true volume of the lesion (as with a temporary displacement due to adherent slough).

Berg *et al.* (1990) suggested that for ulcers situated where there is little subcutaneous tissue, an assessment of surface area alone is probably a satisfactory guide to the rate of healing.

2.1.9 SUMMARY

The reduction of force and the dissipation of energy, are facilitated, in part, by the plantar soft tissues. The plantar padding reduces the acceleration of the calcaneus in the 10-20 msc. interval between the heel making contact and the moment that the calcaneus comes to rest on the ground. Some of the shock at impact is absorbed by tendons and ligaments where it is stored as energy to be returned during gait to reduce the demand on the musculature. Energy is also dissipated during venous return against gravity. This productive interaction is a homeostatic adaptation to man's environment. Homeostasis is by definition a tendency to stability in the normal physiological states of an organism. Where abnormality prevails stability is lost and the interaction becomes unbalanced. When forces exceed the ability to utilise energy productively the inevitable alternative is the destruction of solid structures.

The heterogeneity of tissues from the stratum corneum to bone dictates an inhomogeneity in the distribution of stress and strain. Gibson *et al.* (1976) suggest that these properties may be particularly significant at the skin-subcutaneous tissue interface. The entry of arteries supplying the skin is at right angles to the boundary between the skin and subcutaneous tissue. Deformation of these arteries by strain in the plane of the skin will lead to a paucity of nutrient supply. Gibson *et al.* (1976) postulated that there may be a critical value of stress or strain responsible for micro circulatory failure leading to tissue damage.

The characteristics of ulceration are a valuable indication of the status of an ulcer in its progression or regression relative to the healed state. There are morphological indicators associated with either the active, proliferative or degenerative stages of ulceration. The categorical data describing these events could augment the interval measurement of dimensions. Observations of morphology can be recorded before debridement. Debridement is a necessary procedure if the dimensions of viable tissue are to be recorded. The overlying epidermis of an active ulcer for example will have a smaller aperture than the aperture of the exposed dermal wall of the ulcer.

Ideally the volume of the ulcer should be recorded. An ulcer with a radius of 5mm and a depth of 3 mm which diminishes to a radius of 2.5mm, but retains the same depth, may be recorded as decreasing to half its size if only the radius is measured. The reduction would, however, be a fourfold reduction in volume (the volume of the 5mm ulcer would be 78.5mm^3 whereas the volume of the 2.5 radius ulcer would be 19.6mm^3). Kundin (1989) suggested a formula to calculate the volume of ulceration (horizontal length x longitudinal length x depth x .382). However, the measurement of depth is problematic where there are marked variations in an ulcer floor.

Description would be required of the extent and direction of sinus tracking or the lack in uniformity of ulcer floor. Other methods of volume measurement are unsuitable for field conditions.

There are limitations imposed by recording only the area of ulceration. This may be

compensated for by simultaneously recording the morphological features of ulcers. Such an indication of the healing process, concurrent with the recorded area of ulceration, should enhance the perspective of the resolving or regressing processes.

2.1.10 A RATIONALE FOR ORTHOTIC INTERVENTION

In this section a survey is presented of the salient features of foot structure and function. Pathological foot function is discussed in greater detail to emphasise the logic of orthotic intervention.

2.1.10.1 Foot function

Foot function is a complex component of gait. There are three basic requirements that the foot must resolve if locomotion is to be successful and efficient:

1. The foot must absorb the shock of impact with the ground.
2. It must adapt to environmental and positional changes to maintain stability.
3. It must adjust to become an efficient mechanism for propulsion.

Stability in stance

During the stance phase of gait the skeleton of the foot is constantly in motion developing an adaptable dynamic structure to suit the demands of deceleration, support, equilibrium and acceleration. The subtalar joint is considered to be immobilised by ground reaction forces during static stance. However, a force applied by the gastrocnemius to plantarflex the foot (the only muscle recorded to demonstrate activity during static stance [Root *et al.* 1977]) causes tension forces at the other joints of the foot. During this phase, passive ligamentous function maintains the integrity of the skeleton by resisting tension. In resistance to potential subluxation, the ligaments initially become taught but gradually stretch. Root *et al.* (1977) suggest that there is probably an elastic threshold at which proprioceptive innervation is activated. Momentary muscle contractions are activated which reposition the bones and allow the ligaments to shorten, thereby continuously facilitating the passive protection of skeletal integrity.

The stability of any joint is dependent on the component of force affecting it. During contact with the supporting surface, ground reaction forces interact with the resultant force of body mass, muscle tension and acceleration to exert linear and rotational

forces on bones and joints respectively. Whereas linear forces tend to stabilise joints by compression of opposing bones, rotational forces promote instability at articulating surfaces (Root *et al.* 1977). Logically, therefore, the ideal functional position for any joint in the foot is achieved when the joint is able to function in a position which provides maximum potential for compressional forces with minimal influence of bending forces. Manter (1946) described a longitudinal loading axis from the centre of the trochlea to the second intermetatarsal space. Where joints were angled away from a perpendicular relationship with the loading axis a decrease in compressional force was measured. Manter's description related to stance measurements. It is the authors suggestion that if the loading axis changes during kinetic stance (i.e. when the bones of the foot are in motion while weight bearing), attempts to evaluate the potential stability or instability of joints as an effect of joint position may be confounded by the relative shift of axis as the foot loads from the lateral to medial aspects. However, the underlying principle of the relationship between the angulation of opposing bones and stability was established: i.e. that if a chain of bones was aligned so that all articulations were congruous and perpendicular to the direction of force, then the chain would be stabilised by compression (Manter 1946). The skeleton of the foot is constantly shifting throughout stance and as it does so forces on the proximal bones will angle with reactive forces on distal bones. When the angle is small, compressional force will exceed rotational forces and the joint will be relatively stable. Assuming this ideal is achieved the most economical utilisation of energy will be accomplished (Dananberg 1993).

The interdependence of structure and function determines the efficiency of the foot to serve its purpose at the foot ground interface. When a foot is not functioning correctly, the angles between bones are exaggerated, the angle at which forces will interact across joints is increased proportionately. In such circumstances the effects of rotational forces will dominate and such a foot will be generally unstable. The general deficiency of the foot will compromise the body by high energy demands to impose stability. Root *et al.* (1977) suggest that it is the instability of joints during kinetic stance that presents the primary cause of mechanical trauma to the foot. They explain that as articulating bones are forced to respond to inadequately restricted rotational

forces joints respond by moving beyond their normal range of motion. They may alternatively move in planes of motion contrary to those dictated by their structure and position (Root *et al.* 1977).

Dispersal of weight bearing forces

The significance of the structure of the medial longitudinal arch becomes increasingly apparent when elucidated by Manter's description of the manner and distribution of weight bearing forces (Manter 1946). Forces supported by the foot are transmitted by the tibia through the centre of the talus and then to the medial side of the os calcis, thereby placing considerable demands on the medial supporting structures. By loading the talus, compression forces are dispersed posteriorly to the os calcis and then anteriorly to the metatarsal heads via the tarsus. With distal and transverse dispersion, the magnitude of forces decrease. Manter's findings demonstrate that the medial arch bears twice the weight bearing force expected of the lateral arch. (It is reiterated here that Manter's findings are limited in that they apply to static stance.)

Root *et al.* (1977) demonstrated that the rotational moment of force challenging subtalar stability as a consequence of the medial displacement of the load through the os calcis, is counterbalanced by the invertory effect of the posterior extrinsics. However, Jahss (1991) suggested that shifting the weight bearing load 3 to 4 mm medially will redirect and double the load from one metatarsal head to the next. This may be explained by the effect further medial shifting will have on the stability of the subtalar joint. Any effect that will cause a medial shift of loading will increase the length of the lever arm influencing the subtalar joint. The pronatory moment of force which results may be too great to be counterbalanced by the extrinsic invertors. As a consequence the subtalar joint will be forced to pronate. With pronation of the subtalar joint the aponeurosis is placed under considerable tension and the metatarsal heads are forced into plantarflexion as described earlier. Furthermore, the potential for subtalar pronation to destabilise the foot by causing an increase in hypermobility leads to an uneven distribution of load bearing. This action would explain the increase in load on the metatarsal heads (Dananberg 1993).

Rearfoot complexities

The preceding paragraphs introduce the fundamental role of the talus in determining the configuration of the foot. It has been suggested that the motion of the ankle-subtalar joint complex is analogous with a universal joint mechanism (Mann 1991). Allowing for minor individual variations, the ankle joint axis runs through the inferior tip of the fibular and tibial malleoli. It has a slight lateral incline and is externally rotated in relation to the axis of the knee. The motion at the joint therefore is almost exclusively in the sagittal plane. Frontal plane and virtually all transverse plane motions are transmitted to the tarsus via the talus which, in concert with the calcaneus, cuboid and navicular, translates such forces into triplane motion. This mechanism has been the focus of much study. Current understanding of pedal mechanics, based predominantly on the theories of Hicks, Manter and Elftman, indicates the pivotal role of the rearfoot complex in determining the harmony between locomotion and the environment (Manter 1941, Hicks 1953a, 1953b, Elftman 1960).

Manter's hypothesis suggests that the mid tarsal joint has two axes. The gross frontal plane motion of the forefoot rotates about a longitudinal axis, whilst an oblique axis allows a limited extent of sagittal motion. The extent and direction of motion available is dependent on tarsal midtarsal configuration.

With subtalar pronation (necessary at heel strike to allow for shock absorption and to prepare the foot for adaptation to the weight bearing surface) the talus plantarflexes and adducts whilst the calcaneus everts. The effects are that the talus becomes less congruent with the navicular resulting in reduced stability of the first ray. A further effect is that the oblique axis of the mid tarsal joint moves toward parallelism with the transverse plane thus allowing greater sagittal plane movement in the forefoot. This is facilitated by the planes of rotation around the articular facets of the talonavicular and calcaneocuboid joints becoming more parallel thereby increasing their overall range of motion. (Root *et al.* 1977)

As the leg externally rotates (external rotation of the leg starts after contact) the subtalar joint supinates. With supination the talus dorsiflexes and abducts whilst the

calcaneus inverts. The articular surface and ligamentous constraints of the calcaneocuboid joint dictate that the cuboid also adducts and inverts. This action causes an abduction and eversion of the navicular. A consequence of navicular motion is a further abductory force on the talar head. The effect of this action is that the concave distal articular surface of the talus is forced up against the slope of the posterior joint facet of the calcaneus. Locked in the talocrural mortise the talus cannot continue up this slope so long as the leg remains vertical. The least line of resistance lies in the calcaneus which responds to the force by inverting further beneath the talus. This has the effect of increasing the inversion tilt of the cuboid and the cycle continues until all joints have reached their terminal positions. As a final response the calcaneus externally rotates, very slightly, and dorsiflexes. The planes of rotation around the articular facets of the talonavicular and calcaneocuboid joints become less parallel thereby significantly restricting their overall range of motion (Root *et al.* 1977, Huson 1991, Mann 1991). As a consequence the medial and lateral columns of the forefoot are stabilised by what Root *et al.* (1977) termed the "locking of the mid-tarsal joint".

2.1.10.2 Pathomechanical foot function

The function of the subtalar joint is crucial to the integrity of the foot in kinetic stance. It is necessary that the subtalar joint should pronate at heel strike to allow for shock absorption and to prepare the foot for adaptation to the weight bearing surface (Inman 1981). These attributes are desirable at heel strike but if they are prolonged or excessive the consequences will be pathological (Root *et al.* 1977).

Root *et al.* (1977) suggest that in a foot where the subtalar joint pronates abnormally the angles between bones increase, proportionately increasing the rotational forces that interact across joints. The resulting hypermobility compromises the integrity of the foot leading to joint subluxation and soft tissue trauma

Inman *et al.* (1981) recorded that the angle of inclination of the sub talar joint axis was 40 degrees to the supporting surface (mean 42 degrees, s.d. 9 degrees, range 20-68 degrees n 46). The difference between individuals displaying a subtalar axis angle of 60 degrees and others with an angle of 20 degrees will be profound. If the angle of inclination is low the subtalar joint will predispose the foot to greater frontal plane motion which exposes the foot to tissue trauma. If the angle of elevation of the subtalar axis is high there will be less frontal plane motion displayed but a greater degree of transverse motion will be evident. This factor was elucidated by Kirby (1991) who explained how an increased angle of inclination (as in a cavus foot) was a predisposing factor for lateral ankle sprain. The increased distance of the subtalar joint axis from the ground affects the magnitude of supinatory or pronatory moments due to the increased lever arm for ground reaction forces to initiate motion at the subtalar joint. The potential for injury is increased during incidents of sudden adduction of the centre of mass. Such an event causes an excessive impulse of ground reaction force which being directed toward the centre of mass, acts obliquely on the plantar surface of the foot. With a force applied to the medial aspect of the heel, the obliquity of the ground reaction force will demonstrate an effect relative to the length of the supinatory lever arm: i.e. the longer the lever arm from the point of application to the subtalar joint axis the greater the magnitude of rotatory moment of force

around the subtalar joint.

Since transverse motion in the foot is restricted by friction, transverse rotations are exhibited predominantly in the leg, thus sparing the foot but predisposing the subject to postural problems (Root *et al.* 1977). Translational friction is an essential component of grip and is proportional to the product of the normal force and a coefficient of friction dependent on the properties of two involved surfaces (Bosjen-Moller and Jorgenson 1982). It may be described as a force acting to prevent relative sliding between two contacting surfaces. Whereas friction acts to stop the moving foot, if internal momentum between bone and soft tissue continues shearing stress results (shearing stress acts tangentially to a surface and results in a relative sliding between two surfaces) (Blakeman 1985). In a foot where bones move further than normal, due to hypermobility, excessive shear is produced between bone and underlying soft tissue immobilised by friction.

Thompson (1988) emphasised that the concept of stress should not be confined to consideration of the effects of the application of force to external surfaces. Stress is applied through the full depth of soft tissue on the application of load. Although there is a clear distinction between normal and shear stress, there is a relationship between an increase in normal stress at the surface of the foot and an increase in internal shear stress. External forces are measurable and the distribution of forces as a consequence of gravity and inertia may be recorded but the effects of internal forces present a greater challenge. Stokes *et al.* (1974) recognised the relationship between muscle and ligament tension, forces in joints and stress in bone as mechanisms supporting the application of forces to the foot. They sought to deduce relevant loads and stresses by measuring the geometry of the forefoot, the angle it presented to the ground during propulsion, and vertical load during gait. A result of their study showed that the metatarsals are subjected to an upward shear force and bending moment as an effect of ground reaction. These effects were moderated by counteractive tension in the short plantar ligaments.

Functional deviations from the ideal

Aphasic subtalar pronation, supination and restricted motion have been cited as predisposing factors of pedal and postural symptomatology (Boyd and Bogdan 1989, Neale and Boyd 1989, DiNapoli *et al.* 1990, Dananberg 1993). Root *et al.* (1977) contend that abnormal pronation, or an abnormally pronated position of the foot during kinetic stance, is implicated as the major cause of afore-mentioned symptomatology. They suggest that abnormal pronation may be a response to four factors:

1. Compensation for osseous or soft tissue abnormality of the foot or lower extremity.
2. Response to premature medial loading of the foot.
3. Muscular imbalance of neuromuscular aetiology.
4. Tonic muscle spasm as a response to articular or periarticular pain.

Compensatory pronation

Of these responses, compensatory pronation is the most commonly implicated cause of symptoms (Subotnik 1973a). Of the congenital, developmental or traumatic abnormalities requiring compensatory pronation those intrinsic to the foot include: forefoot varus, forefoot valgus, plantarflexed fifth ray, plantarflexed first ray (which may cause postural instability unless compensated), rearfoot varus and osseous deformities restricting ankle dorsiflexion (equinus) (Burns 1987, Tiberio 1988, Neale and Boyd 1989).

Extrinsic abnormalities of congenital or developmental origin include tibial varum, internal tibial or femoral torsion, inequality of limb length, congenitally or developmentally short gastrocnemius, hamstrings or iliopsoas (Subotnik 1973a, 1973b, Boyd and Bogdan 1989, Neale and Boyd 1989). Neuromuscular disorders that cause the internal rotation of the femur are also implicated (Root *et al.* 1977).

Rearfoot varus

The pathomechanics of rearfoot varus presents an opportunity to describe the mechanism required to compensate for a frontal plane abnormality. When the subtalar joint is in a neutral position (i.e. neither pronated nor supinated with the subject standing in the base of stance) but the calcaneus is inverted relative to the perpendicular midline of the body the condition is termed rearfoot varus (Root *et al.* 1977).

Functional rearfoot varus is the result of extrinsic factors, notably tibial varum or genu varum, where although the subtalar joint is in correct alignment with the tibia, the tibia is malaligned in the frontal plane. A narrow angle of stance in gait may also increase the degree of limb varus thus creating a functional rearfoot varus condition (Boyd and Bogdan 1989, Neale and Boyd 1989). An intrinsic rearfoot varus describes subtalar varus which may be due to Sgarlatto's postulation that an abnormally deep lateral aspect of the talus results in the subtalar joint being inverted relative to the centre line of the body (Sgarlatto 1978). Intrinsic rearfoot varus may also be due to the lack of resolution of varus torsion of the calcaneus during ontogenic development.

Compensatory subtalar pronation for rearfoot varus allows the foot to become plantargrade. Pronation usually occurs early and to excess but the subtalar joint may recover to become neutral or supinated and thereby continue to prepare the foot for propulsive stability. If depronation is delayed due to a demand for excessive pronation or ligamentous laxity, the timing for correct foot function is disrupted (Root *et al.* 1977). Consequently, the foot moves into the stance phase of gait without having adjusted from the mobile adaptive state to the stable state required for maximal effect of compressional forces. The foot may then move into the propulsive phase without the rigidity required for efficient leverage. A further problem arising from compensatory pronation for rearfoot varus is that compensation is required in the frontal plane only. The subtalar joint pronation facilitates frontal plane motion at the mid tarsal joint but this action does not occur in isolation (Manter 1946, Hicks 1953b, Elftman 1960). Motion around the subtalar axis is in three planes therefore whilst permitting motion in one plane it must allow motion in the other two body planes.

Whilst the motion to compensate a deformity may be of benefit the motion that occurs in the other two planes is counterproductive and potentially destructive. Where subtalar motion is restricted it may not be possible to bring the calcaneus into a vertical position. The subtalar joint may still pronate to the end of its range of motion thus everting the calcaneus maximally though insufficiently. The effect is that of a hypermobile inverted foot with stress applied to the lateral and central columns. Peroneal spasm may cause the foot to abduct, pivoting around the fifth metatarsal head, producing a torque reaction from the ground. As a consequence, toe off may proceed from the medial side of the hallux (Root *et al.* 1977).

A further mechanism to provide a stable base of support is the active plantarflexion of the first ray (a functional unit including the first metatarsal and medial cuneiform [Root *et al.* 1977]). If the foot remains inverted with maximum subtalar pronation, peroneus longus may contract to facilitate the plantarflexion of the first ray. A result is that the first metatarsal head is aligned with the lateral metatarsal heads in the same plane (Snidjers *et al.* 1986, 1993, Kirby 1991, Dananberg 1993).

Root *et al.* (1977) described the pathomechanics related to internal femoral torsion to demonstrate the compensatory effects of subtalar pronation to accommodate transverse plane abnormalities. Internal femoral torsion is described as an abnormality in which the lower extremity is caused to internally rotate relative to the hip in its neutral position (Root *et al.* 1971). As an uncompensated consequence of the deformity an individual will walk with feet in adduction (Mittleman 1971). It has been observed that internal femoral rotation is compensated by abduction of the foot whilst the leg remains internally rotated. Abduction of the foot is accomplished by pronation of the subtalar joint. A relative straightening of the alignment of the foot is achieved in the transverse plane but the foot is destabilised and hypermobile as a consequence.

Subtalar pronation as response to premature medial loading of the foot

It has been demonstrated that by midstance forces supported by the foot are directed laterally. As stability of the tarsus and the medial arch is established load is transferred medially prior to propulsion (Manter 1946, Schwartz and Heath 1964, Katoh *et al.*

1983). Abnormalities that cause excessive medial loading of the heel at contact disadvantage the foot. Early or excessive medial loading challenges sub talar stability because the medial displacement of the load through the os calcis is inadequately counterbalanced by the invertory effect of the posterior extrinsics. Any effect that will cause a medial shift of loading will increase the length of the lever arm influencing the calcaneus. Likewise, excessive loading will increase the pronatory moment of force which may be too great to be counterbalanced by the extrinsic invertors. As a consequence the subtalar joint will be forced to pronate to allow calcaneal eversion (Jahss 1991). Root *et al.* (1977) have suggested that common causes for the premature distribution of medial loading include: extreme obesity, external femoral torsion, external tibial torsion, rearfoot valgus, tibial valgum, neuromuscular disorders that maintain the femur in external rotation, an everted calcaneus at heel strike and abnormal verticality of the midtarsal joint axis.

It seems reasonable to suggest that if the midtarsal oblique axis is more vertical than the average 52 degrees suggested by Manter (1946), it will permit greater transverse range of motion. With the forefoot held by friction during stance the talus adducts as the leg internally rotates. Body mass must then be supported by the medial arch (Huson 1991, Mann 1991). The latter structure will be destabilised by medial loading and consequent pronation of the subtalar joint. The result of talar adduction and medial displacement of the tibia will be excessive medial loading with resistance to high internal rotation forces (i.e. shear). These effects are greatly exacerbated by ligamentous laxity seen at its most extreme in Marfan's and Larsen's syndromes but not uncommon in hypermobile pes planus (Root *et al.* 1977). Excess laxity is associated with cyclic destruction of the foot. Permanent stretching results in bone deformation and a shifting of joint axes which results in further ligamentous stretching and ultimately osteoarthritis. Stretching of the spring ligament may lead to the medial deviation of the talar head. Stretching of the plantar and bifurcate ligaments results in mid tarsal laxity and instability. On weightbearing these effects lead to abnormal dorsiflexion and abduction of the forefoot as the entire girding system of the foot is challenged (Huson 1991, Jahss 1991).

Subtalar pronation as a consequence of muscular imbalance of neuromuscular aetiology

Muscle imbalance, which may be a consequence of neurological disorder, may affect the actions of the subtalar joint either directly or indirectly (Root *et al.* 1977). A direct effect involves an imbalance between the invertors and evertors of the foot. Indirect effects, however, result from neurological involvement extrinsic to the foot but affecting gait in such a manner that subtalar pronation is required to compensate. Due to the complexities and individuality of neurological disorders, a review of lower limb function that describes the general effects of neurological disorder is not possible.

Subtalar pronation as a consequence of tonic muscle spasm response to articular or periarticular pain

The pain associated with the inflammatory process may cause tonic muscle spasm. As a natural defence mechanism, this response usually results in the joint being moved away from the position which causes pain. A consequence is that the range of motion is usually restricted giving rise to the term "reflex splinting" (Root *et al.* 1977).

The most common spastic pronator of the subtalar joint is peroneus brevis which is responsible for the condition termed peroneal spastic flatfoot (Harris and Beath 1948, Leonard 1974, Seetharama Rao and Joseph 1994). This condition is commonly related to tarsal coalitions described as fibrous, cartilaginous or osseous unions of tarsal bones (Mosier and Asher 1984). Characteristic foot deformity as a consequence has been described as including a valgus hindfoot, an abducted forefoot and loss of the medial arch. Although uncommon, varus deformities have been recorded as being associated with tarsal coalitions (Seetharama Rao and Joseph 1994).

Root *et al.* (1977) have recorded the combined tonic spasm of peroneus brevis with peroneus longus. When this does occur a peroneal spastic flatfoot will not occur because peroneus longus in spasm will plantarflex the first ray. Consequently, the forefoot will not supinate around the longitudinal midtarsal axis to compensate for the pronated rearfoot. Possible sequelae are that the tibial sesamoid is traumatised and

that a plantar keratoma may develop beneath the first metatarsal head.

Inflammation at the base of the first ray or at the midtarsal joint may excite tonic spasm of peroneus longus. As a consequence there may be insufficient compensatory supination around the midtarsal joint longitudinal axis to align the first metatarsal head in the same plane as the other metatarsal heads. If the forefoot cannot supinate around the midtarsal longitudinal axis the ground reaction inversion force is reflected back into the subtalar joint which will be forced into supination. However, peroneus longus remains in spasm during the swing phase of gait when there is no reaction force to counter the pronatory force of the muscle. Consequently at heel strike the calcaneus is excessively everted such that the supinatory moment of force exerted by the posterior muscles is inadequate to counter the pronatory ground reaction forces.

Demands may be made for compensatory subtalar pronation as an effect of tonic spasm of gastrocnemius or anterior tibialis. Gastrocnemius spasm occurs as a response to inflammation of the plantar or posterior aspect of the heel. The effect is that of an equinus deformity which creates a demand for compensatory dorsiflexion at the midtarsal joint. Such dorsiflexion is made possible by the pronation of the subtalar joint with consequent lowering of the transverse axis of the midtarsal joint to allow greater sagittal plane motion. As a protective mechanism for inflammation causing pain with the plantarflexion of the first ray, tibialis anterior may exhibit tonic spasm. The effect will be as that of forefoot varus deformity. Inversion of the first ray supinates the forefoot around the midtarsal longitudinal axis. Ground reaction eversion forces pronate the forefoot around the longitudinal axis of the midtarsal joint. However, if the inverted medial aspect is still elevated in relation to the lateral aspect the tarsus will continue to evert thereby forcing the subtalar joint into pronation.

The effects of tonic muscle spasm introduced here have been broadly discussed by Root *et al.* (1977).

Compensatory supination

During normal kinetic stance the subtalar joint pronates at heel strike, supinates to its neutral position at midstance and then supinates further to a supinated position at propulsion. Reasons for aphasic supination include central nervous pathology, lower motor neurone pathology, compensation for everted forefoot abnormalities or for equinus deformities in which the heel does not make ground contact.

Due to the complexities and individuality of neurological disorders a review of lower limb function that describes the general effects of such disorders is not presented here. General indications are that where there is a flaccid paralysis of the peroneals, antagonistic supinators may become contracted. An alternative is that clonic muscle spasm of the supinators may cause direct supination of the subtalar joint. Neuropathy generally results in the flaccid paralysis of the musculature innervated by the affected neurone. However continuing stimulus of proprioceptor origin can elicit tonic muscle spasm explained by the continuous excitement of the lower motor reflex arc (Root *et al.* 1977).

Supinatory compensation for forefoot abnormalities

Frontal plane abnormalities of the forefoot including plantarflexed first ray and forefoot valgus deformities are usually compensated by inversion of the forefoot around the longitudinal midtarsal axis. From neutral, the tarsal mechanism essentially only moves into inversion and back. Eversion therefore indicates a return from maximal inversion to neutral. From neutral therefore a full range of inversion is available to compensate an everted forefoot abnormality. If the angle of abnormality is greater than that which can be accommodated by inversion around the longitudinal axis the inventory force will then be reflected back into the subtalar joint. The subtalar joint will then be forced into supination. Compensatory supination for forefoot abnormalities is characteristically late in the stance phase and momentary in execution. More sustained aphasic supination is more strongly associated with tonic muscle spasm or neurological disorders.

2.1.11 THE ORTHOTIC APPROACH TO MECHANICAL MALFUNCTION AND ITS EFFECTS

The general aim of an orthosis is that it should intervene to attenuate the punishing consequences of abnormal foot structure or function. More specific aims will depend on the nature of the underlying problem. The action of some orthoses will be to perform as a substitute for anatomical inadequacy whilst others will aim to alter kinematic function. More specific aims include:

1. The correction of phasic joint kinematics by controlling the extent of subtalar pronation.
2. The redirection and redistribution of force.
3. The accommodation of foot structure to facilitate optimum foot function.
4. The attenuation of effects of uncontrolled sub talar pronation.
5. The distribution of weight over an increased area of the foot.
6. The support and palliation of vulnerable areas of the foot
7. The deflection of pressure from a vulnerable area.
8. Cushioning to reduce impact.

The functional orthosis

The term "functional" when used in this context usually refers to an orthotic device that restricts subtalar pronation. The aim of a functional orthosis is to improve the prospects for the foot to achieve the desirable objective of reaching mid stance with the subtalar joint approximately neutral (i.e. neither pronated nor supinated). If this objective is reached it is reasoned that the foot will be ideally prepared, kinematically, for the demands of the propulsive phase of stance. (Kirby 1992)

An appropriately angled wedge beneath the heel effectively brings the supporting surface into contact with the inverted position of the calcaneus at heel strike. The angle of the wedge is calculated by measuring the angle between the supporting surface and the calcaneus when the subtalar joint is in its neutral position (Blake 1986). A response to this approach is that the subtalar joint will pronate but not to excess. The angle of the wedge may be increased to accommodate ligamentous laxity

which would exacerbate the tendency of the subtalar joint to pronate (Root *et al.* 1977).

Functional devices per se were not used in this study, consequently a detailed description is not relevant here. However the principle of counteracting subtalar pronatory moments was used. Orthoses that do restrict or attenuate the effects of subtalar pronation are likely to affect the subsequent function of the foot. Such devices are, therefore, "functional" in their action. A term commonly used for orthoses that are not prescribed principally to alter foot function is "accommodative". The term has passive connotations and does not project the potential for such devices to initiate dynamic effects.

Individuality dictates that orthoses require consideration of peculiar specifications. Orthoses are prescribed on consideration of a combination of criteria. The prescription will be based primarily on a subject's foot structure and gait.⁶ There are basic components that can be incorporated in the manufacture of an orthosis. These are commonly used in combinations, however, each component is specific and may be applied in isolation, where appropriate.

The tarsal platform (Fig 5)

This device is designed to extend from the anterior edge of the heel to a line immediately proximal to the metatarsal formula (the arc in which an individual's metatarsal heads lie in the transverse plane) where the full thickness of the material (4 to 5 mm) is bevelled to accommodate the metatarsal heads. The posterior edge is shaped to the heel and bevelled to a width of approximately 1 cm. As a platform of firm material, it enlarges the weight bearing area of the foot and relieves the loading on the heel and metatarsal heads. Its primary function is to bring the lateral border of the foot into contact with the supporting surface. In so doing it imposes a slight evortory force on the foot. As a basic structure, it is indicated for pes cavus feet which exhibit excessive metatarsal loading and lateral instability but is contra

6. Other physiological considerations will be arterial supply, venous return and neurological status. An assessment of intellect and psycho-social factors is also required

indicated for feet with fixed varus abnormalities (Neale and Boyd 1986). The author suggests that it should not be used where feet demonstrate grossly abnormal lateral loading (as in foot drop). The tarsal platform is the base for a number of modifications designed to meet individual requirements.

The tarsal cradle (Fig 6)

This is an extension of the tarsal platform to include a "valgus dome" and flange. The term "valgus" is commonly used to refer to the position of the foot when the subtalar joint is pronated. The "valgus dome" is structured to address this abnormality. The structure is modelled to fill the concavity of the medial longitudinal arch thereby maintaining the architecture of the arch as it resists the effects of abnormal (late or excessive) subtalar pronation (Neale and Boyd 1986). The author recommends that it should extend medially, as a flange, to cover the sustentaculum tali, the talar head and the tuberosity of the navicular. From its highest point, at the tuberosity of the navicular, it should slope inferiorly to the base of the first metatarsal head. An indication from this suggestion is that the valgus dome should be constructed with particular attention to individual variability.

A well-designed tarsal cradle will support both the medial and lateral borders and present resistance to hypermobility of the foot. (Neale and Boyd 1986) When the calcaneus everts it causes an axial rotation of the cuboid which destabilises the lateral column and consequently causes hypermobility of the fourth and fifth metatarsals (Huson 1991). The tarsal platform supports the medial, plantar and posterior process of the cuboid which underlaps the calcaneus. This support adds resistance to calcaneal eversion and in so doing enhances the stability of the lateral column (Neale and Boyd 1986). In a similar fashion, support beneath the tuberosity of the navicular and sustentaculum tali should resist the adduction and plantarflexion of the talus and the eversion of the calcaneus respectively. These effects should contribute to the stability of the medial column and the foot in general.

The salient feature of the tarsal cradle is to facilitate efficient functioning of the first ray. Assuming normal phasic activity, as the leg externally rotates and the tarsus

inverts the second metatarsal follows and assumes an inversion tilt. Responding to ground reaction force the third and fourth metatarsals will dorsiflex to the extent allowed by individual tarsometatarsal connections. This is usually sufficient to allow the metatarsal heads to lie in a common transverse plane (Huson 1991).

As the lateral rays dorsiflex in response to ground reaction, the medial side of the foot remains tilted in inversion. To attain a plantigrade attitude and stabilise the foot for propulsion the first ray must plantarflex. The first ray has a triplane axis (the amount of transverse motion however is clinically insignificant (Root *et al.* 1977). As the first ray plantarflexes therefore, it also everts. The torsional twist around the second metatarsal head contributes to a tightening of the support structures of the medial arch (Mann 1991). The medial arch is simultaneously heightened by the plantarflexion of the first ray and extension of the digits (Kirby 1991b). Whereas the dorsiflexion of the lateral rays is principally a passive response to ground reaction, the plantarflexion of the first ray is dynamic. Efficient first ray function is dependent on a number of structural and functional variables (Root *et al.* 1977).

In a supinated position the first cuneiform and the base of the first metatarsal are elevated relative to the cuboid. Using the stabilised cuboid as a pulley, the plantar direction force of peroneus longus is enhanced by the increased angle of approach to its insertion thereby stabilising the first ray at its base. Its function is also to synergise with the actions of abductor hallucis and flexor hallucis to bring the ray into plantarflexion. In so doing maximal benefit is achieved from compressional forces to stabilise the medial kinematic chain in preparation for propulsion (Root *et al.* 1977, Huson 1991).

The extent to which the first ray must plantarflex will depend on the range of inversion, the width of the foot and the length of the first metatarsal in relation to the second metatarsal. The first two variables need little explanation. The height of the medial tilt will be determined by either factor and clearly the amount of plantarflexion required will be relative to the height of medial border (Snijders *et al.* 1986).

The relevance of the second ray in relation to first ray function is that, independent of other factors, a short second metatarsal will impose a limit on the ability of the first metatarsal to plantarflex. If the second metatarsal is short there may be insufficient clearance for the posterior translation of the first metatarsal over the sesamoids. The problem of a second metatarsal that is too long is also significant. Although allowing ample clearance it imposes an excessive demand for plantarflexion of the first ray in order to attain ground contact (Root *et al.* 1977).

The effects of excessive or aphasic subtalar pronation on the integrity of the foot are multifarious (Reigler 1987). Focus is given here, however, to the effects on the first ray. If the medial column is destabilised due to subtalar pronation the first ray will dorsiflex in response to ground reaction. As a consequence the angle of approach of peroneus longus will be reduced. Having lost mechanical advantage peroneus longus will be unable to effect adequate plantarflexion of the ray and the integrity of this crucial mechanism is compromised. The second or third metatarsal heads are exposed to excessive compressional and shearing stress (Root *et al.* 1977).

Facilitating first ray function is a fundamental aim if forefoot integrity is to be maintained (Kirby 1991). By supporting the structures that maintain the optimal height of the arch it is reasoned that the dynamic features of first ray function will be promoted. This may be the most important function of the tarsal cradle.

The author suggests that if the tarsal cradle is extended medially and posteriorly to include a partial heel meniscus this will benefit the objective of subtalar pronation control. By including a medial wedge a supinatory moment will oppose the pronatory moment around the subtalar axis (Kirby 1992, Fergusson and Blake 1994). This effect will inhibit, if not prevent, the eversion of the calcaneus. Other modifications can be made to address individual specifications.

The metatarsal bar

The metatarsal bar is shaped to conform to the metatarsal formula and is situated immediately proximal to the metatarsal heads (Neale and Boyd 1986). The author

suggests that if a foot has been damaged such that the osseous structures of the forefoot no longer conform to normality, a metatarsal bar can be shaped to correspond with the tread line of the foot. With such a foot the bar is positioned immediately proximal to the treadline. The bar can be incorporated onto a tarsal platform or a tarsal cradle (Fig 5). It can also be used independently of other options.

The author suggests that the action of the metatarsal bar is that it should shift the treadline posteriorly, away from a vulnerable or traumatised area, to a less vulnerable area of the foot. In so doing it will mimic the pivotal role of the metatarsal heads. It must, therefore, be constructed to an optimal height to allow clearance of the vulnerable area. These devices may be particularly useful for feet that no longer demonstrate a normal heel toe gait.

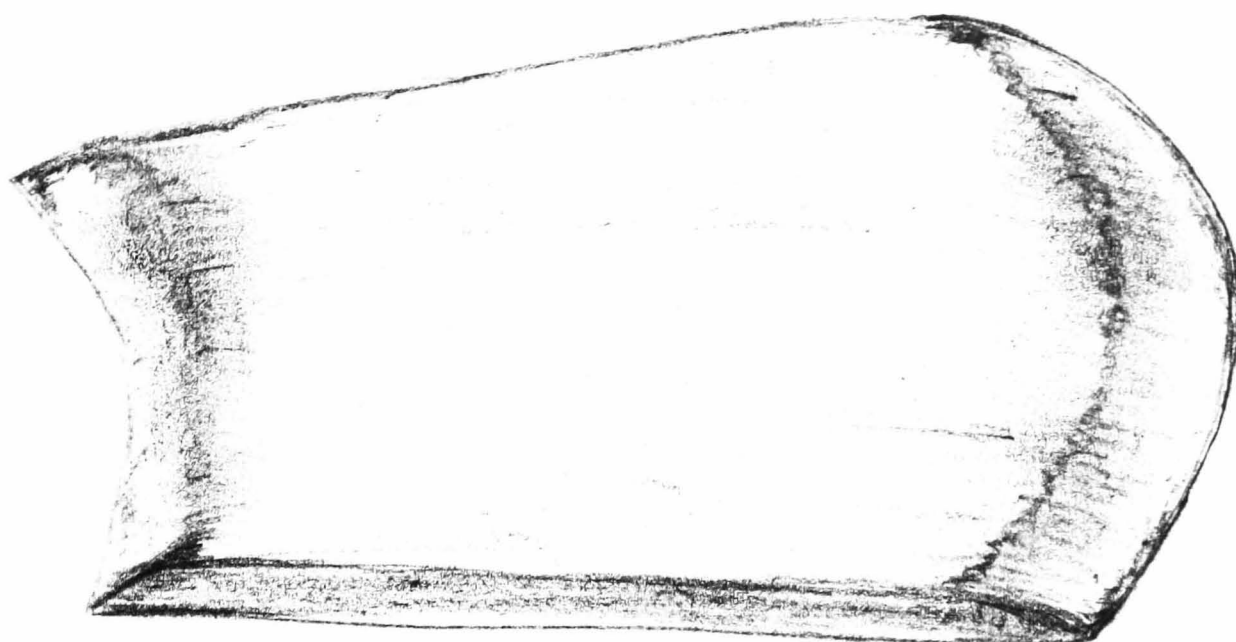
The plantar metatarsal pad (Fig. 7)

The full thickness of a metatarsal pad (PMP) extends from beneath the heads of the three central metatarsals to two thirds of the length of the metatarsal shafts. The anterior edge conforms to the metatarsal formula. It is bevelled from the metatarsal heads to extend beneath the anterior plantar fat pad, to a distance immediately proximal to the webbing of the toes. The lateral and medial edges are also bevelled from the area beneath the second and fourth metatarsals to the medial and lateral aspects of the forefoot respectively. A 1 cm bevel extends from the posterior limit of the full thickness of the pad. The effect is, that on weight bearing, the central metatarsals are elevated. The load on the metatarsal heads is relieved due to the combination of elevation and an increased area of weight bearing (Neale and Boyd 1986).

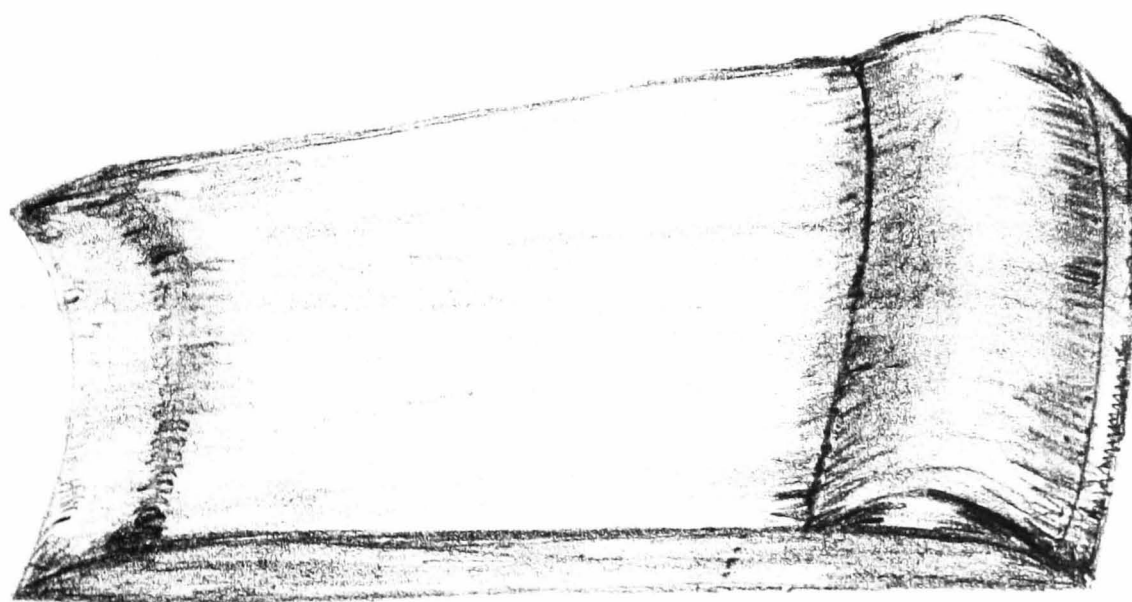
Where feet are compromised by the chronic fixation dislocation or subluxation of the metatarsophalangeal joints, the PMP is applied to palliate the metatarsal heads by redistributing the load. Where a foot presents with mobile claw toes or retracted toes the metatarsals are forcibly plantarflexed (Root et al. 1977). In the action of elevating the metatarsals, the PMP assists by correcting the alignment of the metatarsal heads. The PMP can be modified to palliate the first or fifth metatarsal head or any other

Figure 5

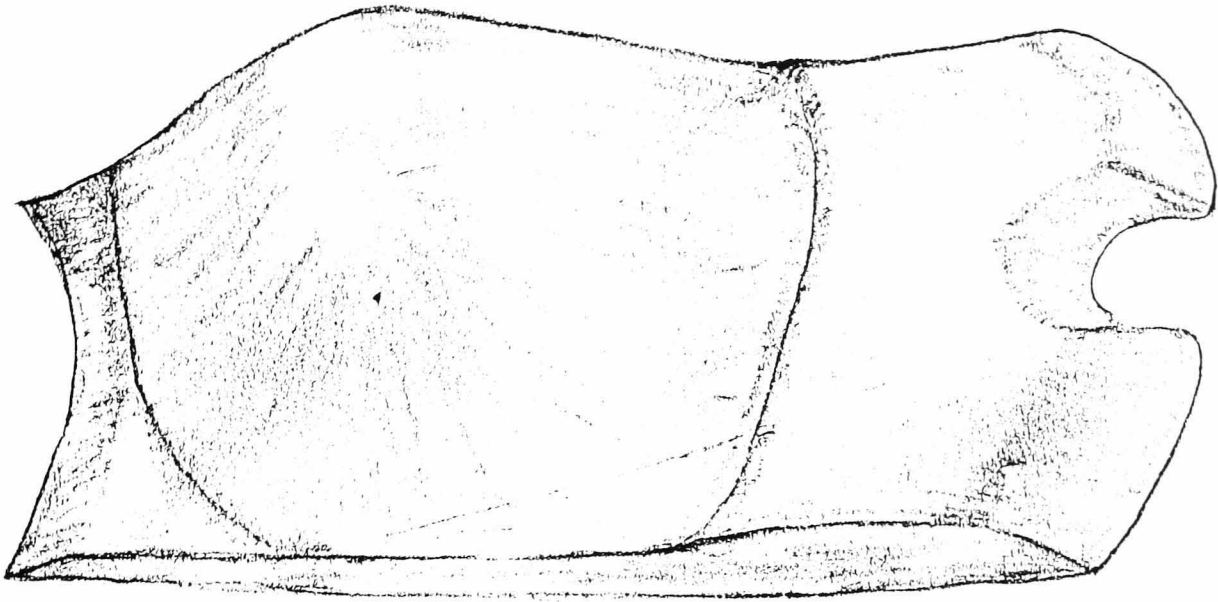
Tarsal platform



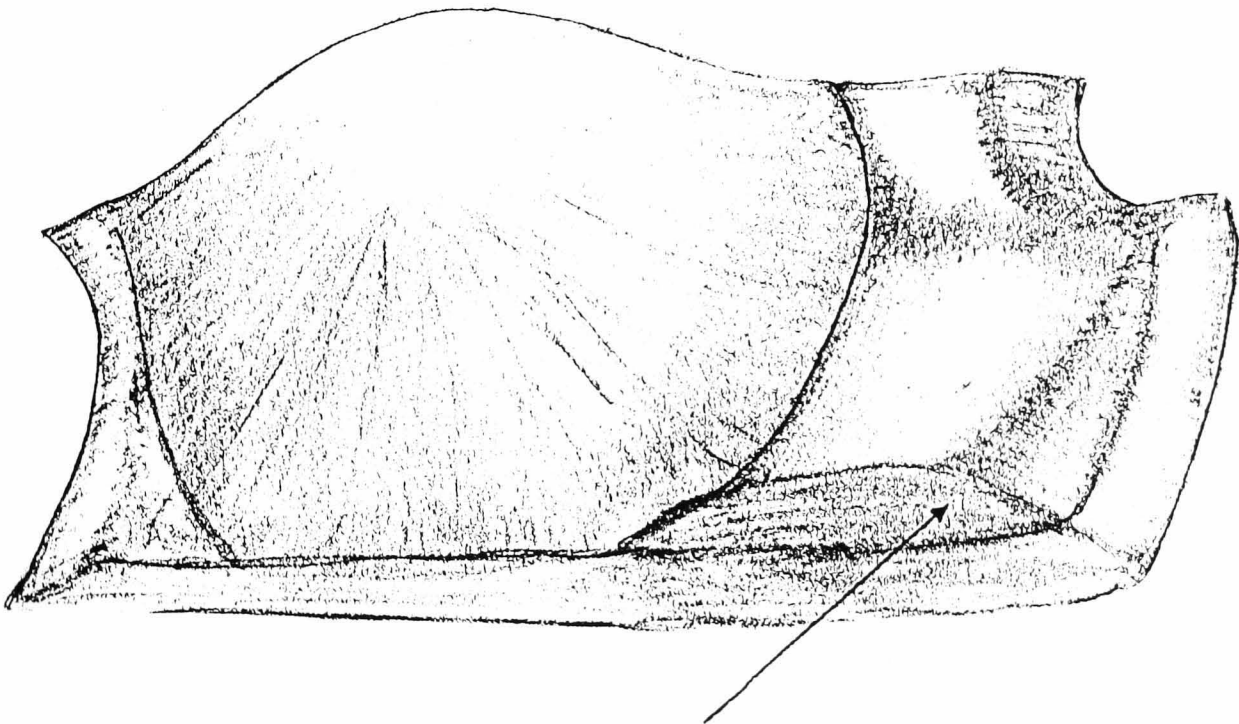
Tarsal platform incorporating a metatarsal bar



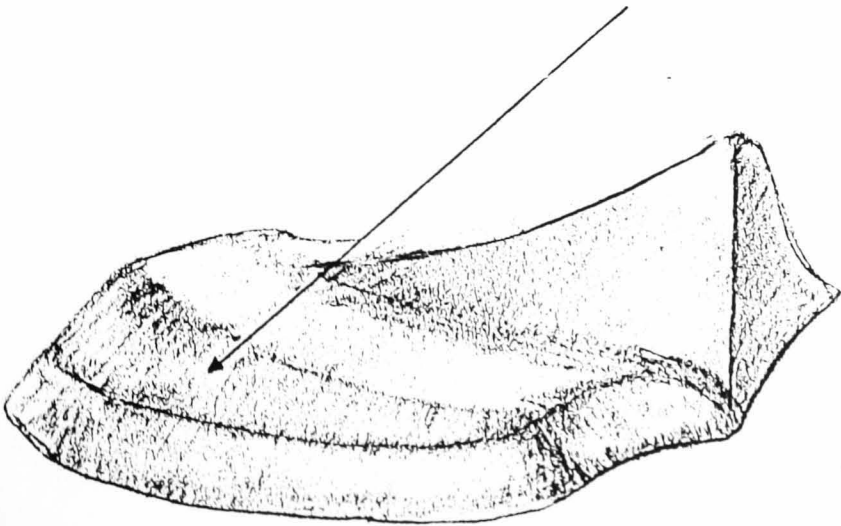
Tarsal cradle incorporating cut away for pressure deflection.



Tarsal cradle incorporating forefoot modification and cut away for pressure deflection.



Forefoot Wedge To Accomodate Forefoot Valgus Deformity



Anterior View

metatarsal head in isolation. The width of the PMP is extended so that the full thickness of the PMP supports the first and fifth metatarsals. An appropriate shape, conforming to the metatarsal head, is cut from the PMP and bevelled to allow the metatarsal head to be accommodated in the cut away area. The effect of a "U" or "wing" shaped section cut away from the PMP is that pressure is deflected from the vulnerable metatarsal head to the PMP and other metatarsal heads (Neale and Boyd 1986).

The author suggests that the PMP can be used in isolation where digital deformities, and consequent plantarflexion of metatarsal heads, are not associated with rearfoot malfunction. Alternatively the properties of the PMP can be included to extend the action of a tarsal cradle.

Digital splints (Fig.8)

The excessive extension and flexion of digital deformities requires the reciprocal action of dorsoplantar corrective pressure. An orthodigital splint usually covers the three middle toes. The dorsal element extends to cover the proximal phalanges and thereby restricts excessive extension whilst the plantar element extends beneath the intermediate and distal phalanges to inhibit flexion. Individual digits are held separately in anteroposterior grooves in the inner surfaces of both pads. Axial rotation and mediolateral deviation are countered by the design of the splint and the corrected positions of adjacent toes. These devices may be used for the protection of apices and may assist in the correction of mobile claw toe deformity (Lorimer and Neale 1986).

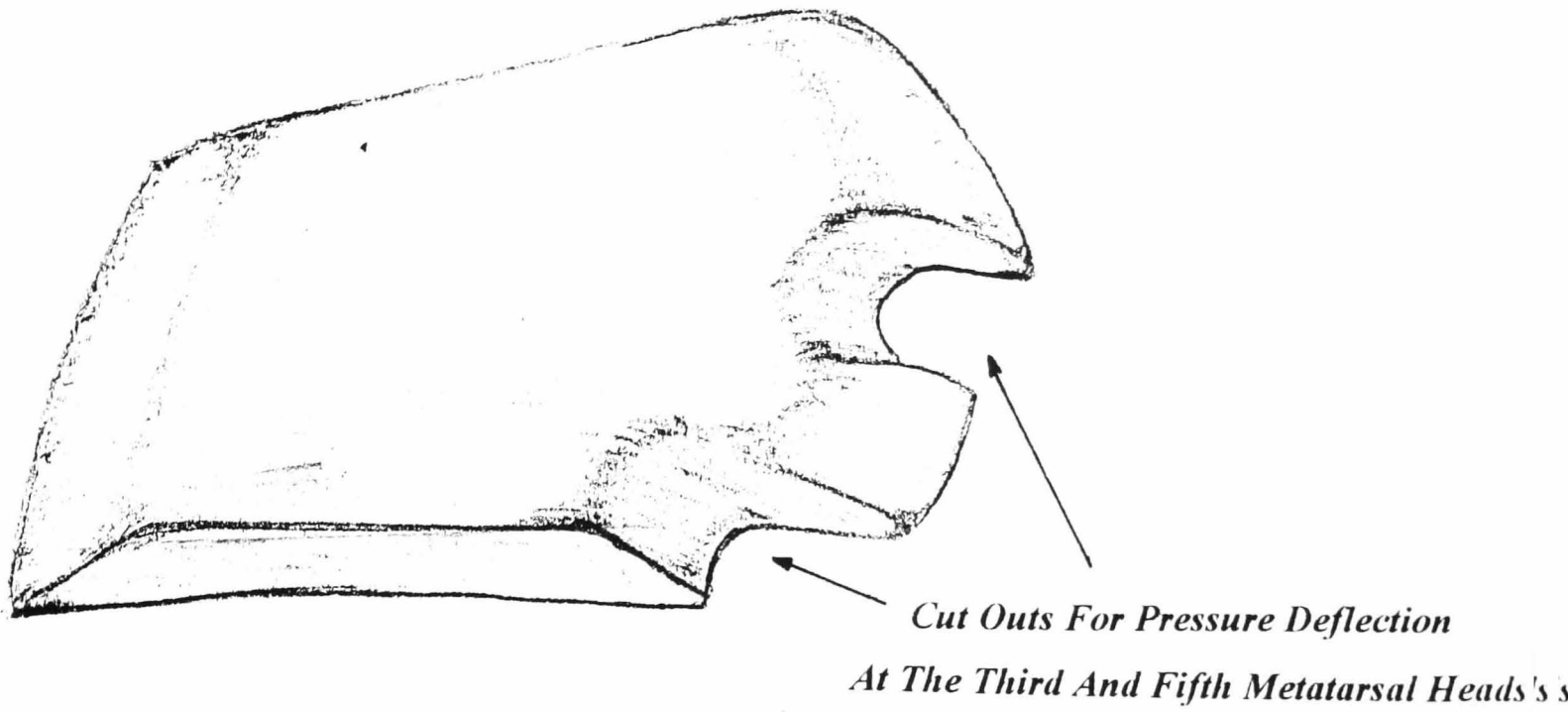
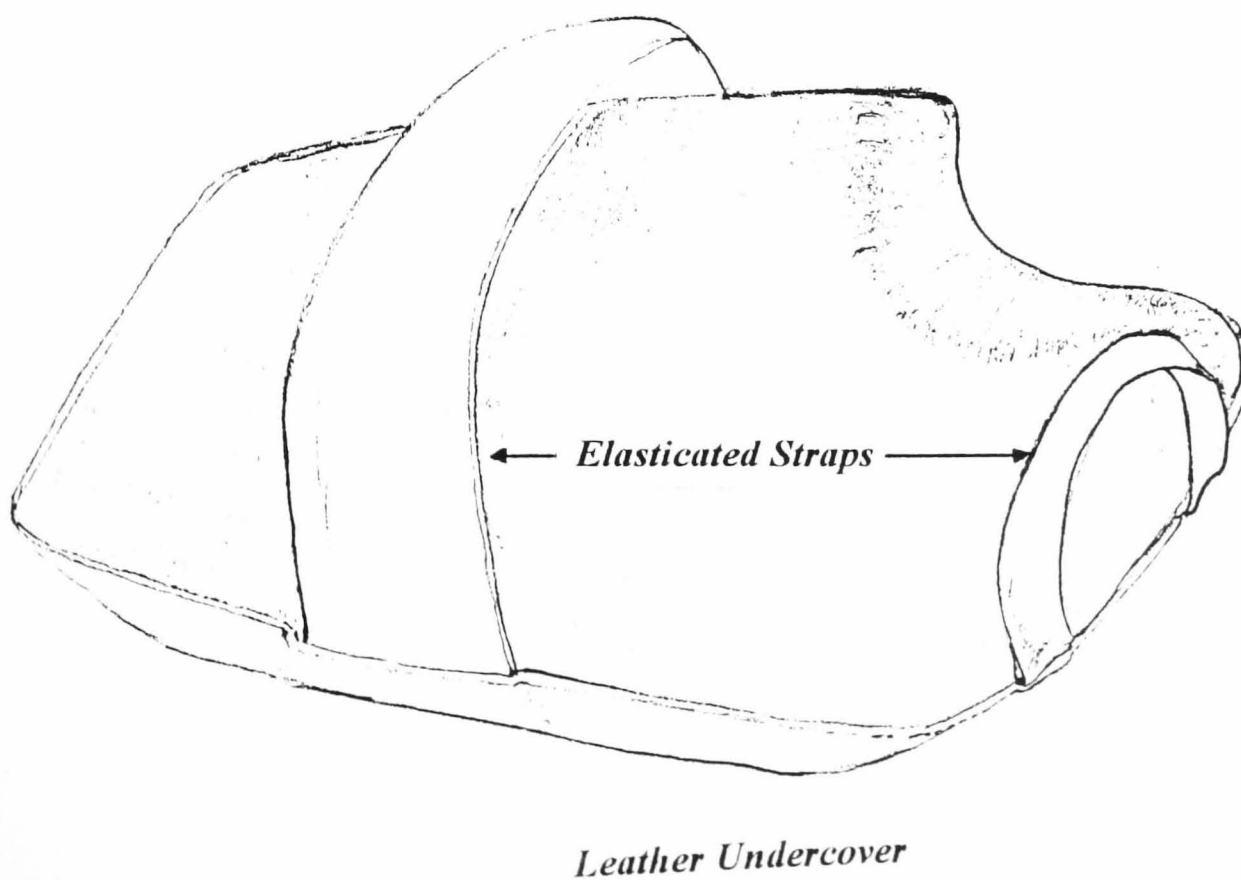
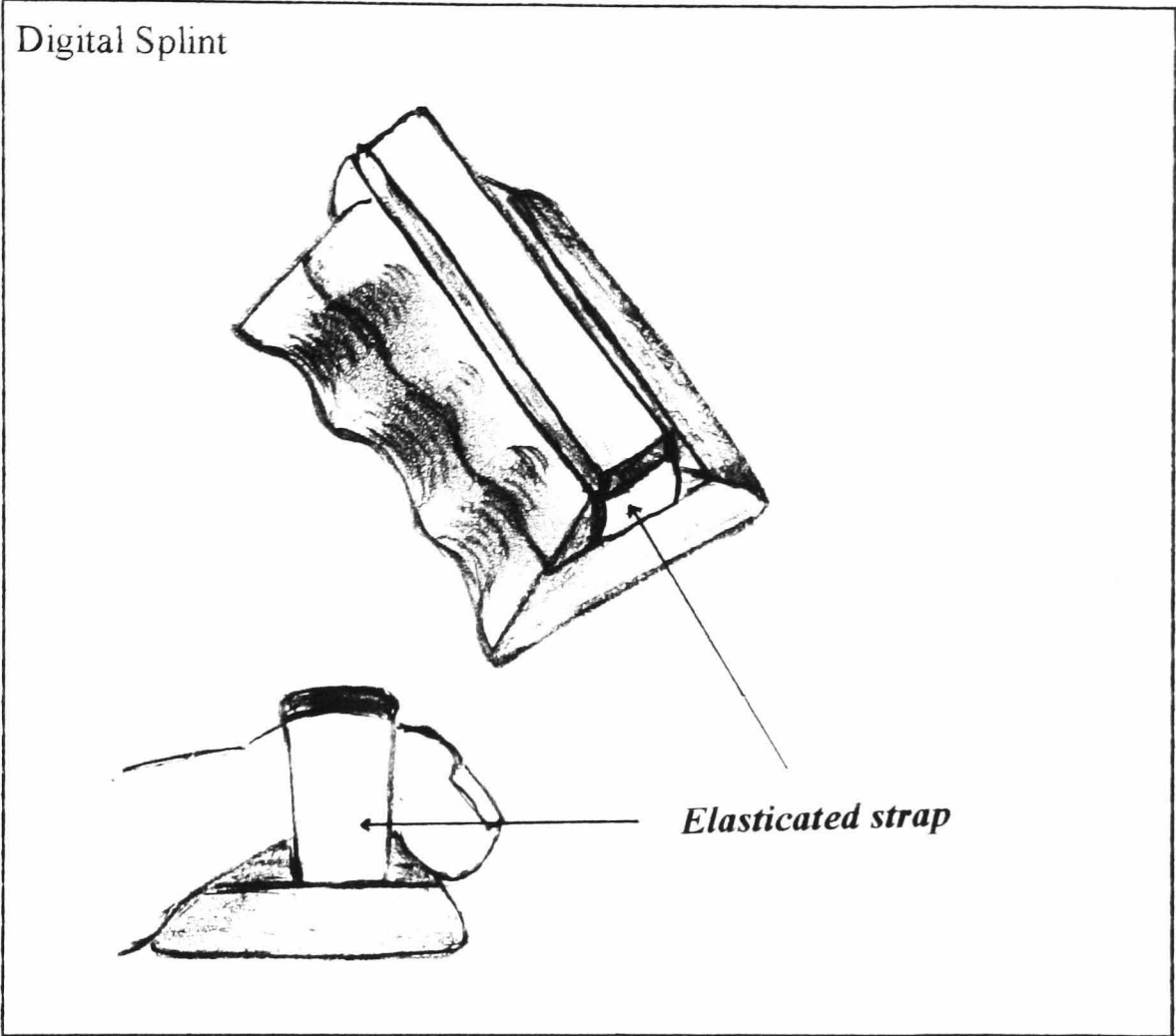
Figure 7***Plantar Metatarsal Pad******Removable Plantar Metatarsal Pad***

Figure 8



2.2 METHOD

A controlled trial was designed. Following ulcer assessments and biomechanical examinations (see appendix 5), an experimental group was supplied with orthoses. The control group was not supplied with orthoses. The groups were compared on the area and morphology of ulceration. These variables were recorded at assessment periods which began in July 1993 and were conducted at three monthly intervals until December 1994. (For assessment procedures please see section 2.2.5.)

It was accepted that the control group would also be supplied with orthoses if it was demonstrated that the intervention was beneficial within a nine month period. In compliance with this condition the control group were supplied with orthoses by the physiotherapy department in March 1994. The trial continued and the effects of orthoses supplied by the author were compared with those supplied by the physiotherapy department. The affects of orthoses on recurrence rates was also recorded.

2.2.1 RELIABILITY AND VALIDITY

Following ulcer assessments in July/August 1993 a second collection of data was recorded in September 1993. On this occasion, the intervention was reviewed to ensure the well being of experimental subjects. At this assessment, data was collected by the author and a physiotherapy technician. The procedure was conducted as a blind trial, to establish inter-observer reliability comparing the findings of the physiotherapy technician with those of the author. (Please refer to Appendix 2 for details.)

A Comparison of the effects of orthoses supplied by the physiotherapy technician with those supplied by the author presented an opportunity to test the repeatability of the method.

2.2.2 DATA STORAGE

Individual details of relevant medical and social information were compiled and filed as hard copies. These *Subject Records* were maintained and updated by me.

Information relayed to me, during interim periods between visits to Kondhawa, included problems with orthoses, as reported by subjects, changes of foot wear and medical intervention.

Data describing ulceration, recorded at three monthly intervals, was coded and stored using Quatro Pro database software. Duplicate data were also stored on individual record sheets maintained as hard copies within subjects' record files.

2.2.3 STATISTICAL ANALYSIS

The decision to use non-parametric tests was based on the knowledge that sample selection was not random and that a wide range of variables may have affected the results..

The Mann-Whitney 'U' Test

This test was used as it is considered a distribution free analogue of the T Test. It has been suggested that it tests a broader null hypothesis than the T Test and that it may be a more powerful test (Neave and Worthington 1988, Howel 1989). The null hypothesis tested is that random samples were taken from identical populations. The test is particularly sensitive to differences in central tendency and rejection of the null hypothesis is interpreted as indicating such a difference. A limitation may be that because the null hypothesis assumes that the two populations are identical, some other population difference could determine rejection.

The Wilcoxon Signed Ranks Test

This is a distribution free analogue of the T test for matched groups or paired scores. It tests a null hypothesis that samples were drawn from identical populations where the distribution of difference scores, for each pair of measurements, would be symmetric around zero.

χ^2 Test of Association

χ^2 was used primarily to compare sets of categorical data. It has been argued, that as a conservative test, χ^2 produces few type 1 errors even with small frequencies. The cautioning of Camilli and Hopkins (1978) was accepted. They suggested, that when a sample size is small and the resultant expected frequencies are small, the test has little power to detect false null hypotheses. Where contingency tables had expected frequencies that were too small for the χ^2 test to be valid, *Fisher's Exact Test* was used. The calculations to find a critical value in Fisher's test is dependent on the marginal totals being fixed. Because the sample number will be known, the row totals will be fixed but column values will vary according to responses given. Since Fisher's test is the only method that has been devised for analysing small samples this difficulty has traditionally been ignored (Neave and Worthington 1988).

Spearman's Rank Correlation

This test was used as a non-parametric analogue of Pearson's product-moment correlation (Howel 1989). In practice, Spearman's formula yields the same result as Pearson's formula. Howell (1989) points out, however, that where there are tied ranks the logic of Spearman's formula is distorted and may be invalidated. In such cases it is recommended that responses with tied scores are assigned ranks which are the average of the ranks for which they tied and then to continue by using Pearson's formula. The confidence limits for the correlation (r_s) can be constructed using Fisher's Z transformation. Arcus tests the null hypothesis that $r_s = 0$.

2.2.4 SAMPLE SELECTION

Of the outpatients and employees at Dr Bandorawalla Leprosy Hospital, individuals known by the physiotherapy technician to present with ulcers, were asked whether they were willing to participate in the trial. Seventy-one subjects consented and were included in the trial. All subjects presented with sequelae of leprosy including anaesthesia and plantar ulceration.

The criteria by which subjects were considered to be suitable for orthotic therapy excluded bed rest patients, patients being treated with plaster casting, patients

presenting with non-superficial bacterial infection (acute or deep seated osteomyelitis) or patients for whom specialised orthopaedic footwear had been prescribed. Of subjects who were approached only one declined the opportunity to be included in the study. Assignment of subjects to the experimental group was dependent on the mutual availability of subjects, the interpreter and the researcher for the supply of orthoses (patients were not requested to seek leave from employment. The interpreter also had other duties to perform).

Thirty-seven subjects were fitted with orthoses and were allocated to the experimental group. Thirty-four were not offered orthoses and were allocated to the control group. By March 1994, 5 subjects had dropped out of the Experimental Group⁷ and one further subject was excluded due to intervention with plastercast treatment. These exclusions reduced the number of subjects to 31 reducing the number of ulcerated feet for analysis to 35 and the number of ulcers to 40 (four feet presented with multiple ulcers). Three subjects had dropped out of the Control group⁸, reducing the number of subjects to 31, the number of ulcerated feet for analysis to 35 and the number of ulcers to 39 (four feet presented with multiple ulcers).

Table 2: Subjects Maintained in the Programme From July 1993 to March 1994

	Experimental Group	Control Group
Subjects	31	31
Feet	35	35
Ulcers	40	39

7 Experimental Group: 3 subjects had left the area. 2 subjects had destroyed their devices and chose not to have them renewed.

8. Control Group: 3 subjects had left the area

2.2.5 ASSESSMENT PROCEDURES

Deformity

An index of foot deformity was designed as an alternative to the less comprehensive though widely used WHO disability classification⁹. The index of foot deformity was formulated to facilitate a comparison between the deformities presented by both groups. Individual variations were considerable, however, classification was made by grouping the most common deformities. This broad classification was based on the degree to which subjects are likely to be compromised by abnormality. Where all other variables are similar, the author considered subjects with grade 1 deformities to be less compromised than those with grade 5 deformity. (See Figure 9) Although classification was based on easily identifiable abnormalities the validity of the scale is limited as no intra-rater test of the procedure was undertaken.

Grade 1 Anaesthesia only.

Grade 2 Loss of lesser toes or digital function.

Grade 3 Loss of hallux or hallux function.

Grade 4 Reabsorption or partial reabsorption of more than one metatarsal head.

Grade 5 Short foot.

Sensibility testing

During the initial planning stages of the project it had been considered that a sensibility test protocol should be designed that would include a detailed examination of cutaneous modalities at the onset of the trial and at its close. There were two reasons for considering this proposal.

1. It seemed possible that subjects agreeing to participate could demonstrate unstable patterns of sensory loss. This is explained by the observation that the sensory

⁹ Hands and Feet

Grade 0: No anaesthesia, no visible deformity or damage.

Grade 1: Anaesthesia present, but no visible deformity or damage.

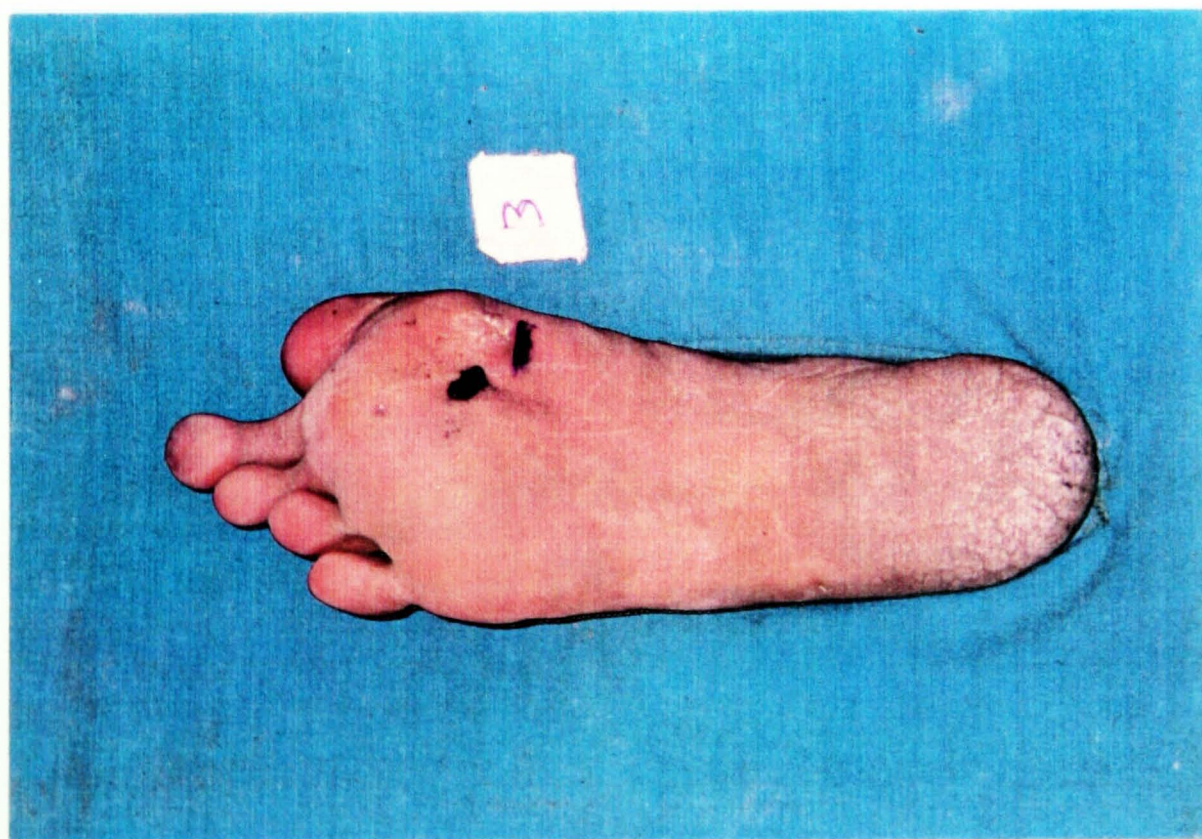
Grade 2: Visible deformity or damage present.

(WHO 1988)

Figure 9.1



*Grade 2 deformity:
Loss of toes or digital function.*



*Grade 3 deformity:
Loss of hallux or hallux function.*

Figure 9.2



*Grade 4 deformity:
Reabsorption, or partial reabsorption, of more than one metatarsal head.*



*Grade 5 deformity:
Short foot.*

status of patients under multi drug therapy can vary. Temporary aberrations in sensory status are not an uncommon feature during periods of lepra reaction. Patients may, therefore, present with sensory impairment at assessment, yet sensibility may return following treatment for reaction. Sensory loss may also become more extensive as a degenerative effect of lepromatous leprosy.

2. The pattern and extent of sensory loss, amongst cured patients, is associated with the disease type implicated. Patients may demonstrate partial loss of selective modalities according to the extent of neuropathy.

On arrival at Dr Bandorawalla Leprosy Hospital it became clear that there was an extensive population of "cured" patients with sensory impairment. It was suggested therefore, that patients currently undergoing treatment should be excluded. Since the presentation of plantar ulceration is commonly considered to be an indication of leprous neuropathy (Klennerman *et al.* 1990) it was not considered essential to conduct exhaustive sensibility tests. Lack of response to pain, pressure and vibration using techniques described by Bickerstaff and Spillane (1989) and Watson (1989) were considered sufficient to establish that feet presenting with ulceration were anaesthetic. A 128 Hz. Tuning fork was used to test vibration and the pin prick test was applied to test for pain response (Bickerstaff and Spillane 1989).

The recommendation for the testing of plantar pressure perception, still advocated by ILEP in 1994, was implemented (applying a ball point pen to a depth of between 1 and 2 mm). Findings relating to sensory loss and observations of deformity were recorded diagrammatically on foot maps as described by Watson (1989). Since all subjects would present with established neuropathy it was not considered necessary to implement a test-retest procedure at the culmination of the trial.

Ulceration

Ulcer site

At the initial assessment, the sites of ulceration were recorded for inclusion in the Subject Record files. Reference to specific anatomical landmarks was made unless the foot was severely deformed.

Ulcer Size

After recording the number and site of lesions, individual ulcers were measured using precision callipers and a metric rule. The area of ulceration was calculated using the following dimensions:

The greatest distance between 2 points on the edge, longitudinally.

The greatest distance between 2 points on the edge, horizontally.

The area of ulceration was then calculated using the formula:

(Horizontal length + Longitudinal length) x .785¹⁰ (Johnson 1993, Kundin 1989)

Ulcer Morphology (See Fig 10)

Ulceration was further described by categorical rating of edge and surface morphology following criteria described by Wall (1979). A decision was made not to categorise morphology by rank (i.e. "1" being the most favourable) as this may have biased the assessment procedure.

Table 3: Categorisation of Ulcer Morphology

Rating	Edges	Rating	Surface of the ulcer floor
1	Undermined	5	Adherent slough
2	Indurated and punched out	6	Slough and granulation
3	Shelved	7	Granulation
4	Rolled	8	Perforating
		9	Hypergranulation
		10	Malignant proliferation

2.2.6 SUPPLY OF ORTHOSES

Following ulcer assessment, the experimental group subjects were prescribed orthoses. The devices issued incorporated features aimed at addressing both palliative and functional demands (examples of the devices used are presented diagrammatically

10 .785 = π divided by 4

please see Figs. 5 to 8).

Prescription was based on observations of gait and examination of foot structure. (See Appendix 5) The choice of materials used was determined by local supply. Devices were fabricated from micro-cellular rubber to accommodate the requirements of individual subjects. The supply of elasticated removable devices was limited to subjects demonstrating an uncompromised vascular supply and sufficient manual dexterity. All other devices were adhered to subject's foot wear.

The subject's choice of foot wear was respected, however, if damaged it was either replaced or repaired. All changes to, or of, footwear over the experimental period were recorded.

Table 4: Orthoses Supplied to the Experimental Group: July/August 1993

Devices supplied	Quantity
Tarsal Cradle incorporating cut away sections for pressure deflection	17* ¹
Tarsal cradle incorporating anterior rocker bar	2
Tarsal platform with window	1
Plantar metatarsal pad with cut away for pressure deflection	13* ²
Heel cushion	2

*¹ 3 devices incorporated forefoot modifications for frontal plane abnormalities

*² 6 devices were removable

2.2.7 ULCER DRESSINGS

The use of gauze swabs, secured by tape or minimal bandage, was demonstrated to Experimental Group subjects. Where ulcers did not present with excessive exudate Experimental Group subjects were encouraged to dress ulcers with zinc tape. This approach has been shown to demonstrate an effect not significantly different from gauze bandage (Walton *et al.* 1986). Control Group subjects continued to dress ulcers with gauze bandage.

The Morphology Of Ulceration

Figure 10.1

Edges



Undermined edges



Indurated edges

Figure 10.2



Shelved edges



Rolled edges

Figure 10.3

The Morphology Of Ulceration

Surface of ulcer floor

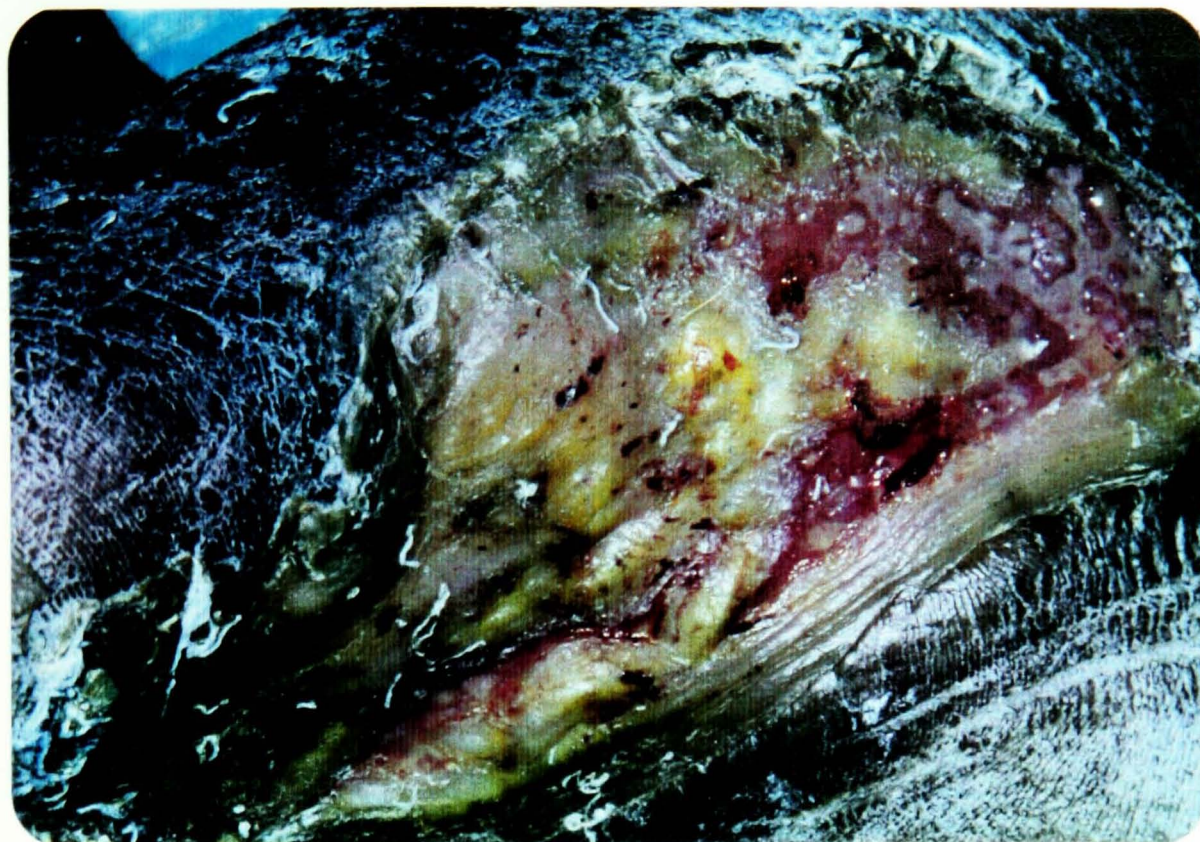


Granulation



Slough and granulation

Figure 10.4



Adherent slough

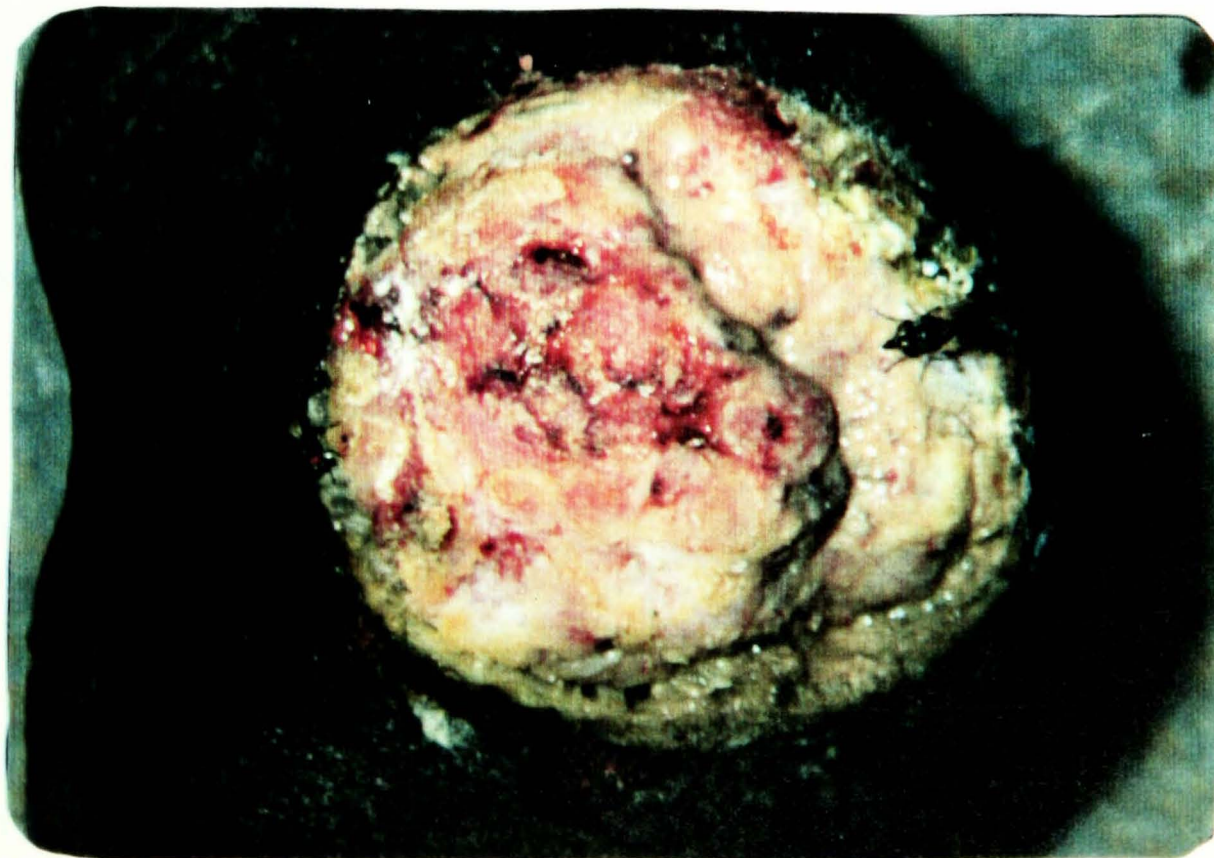


Hypergranulation

Figure 10.5

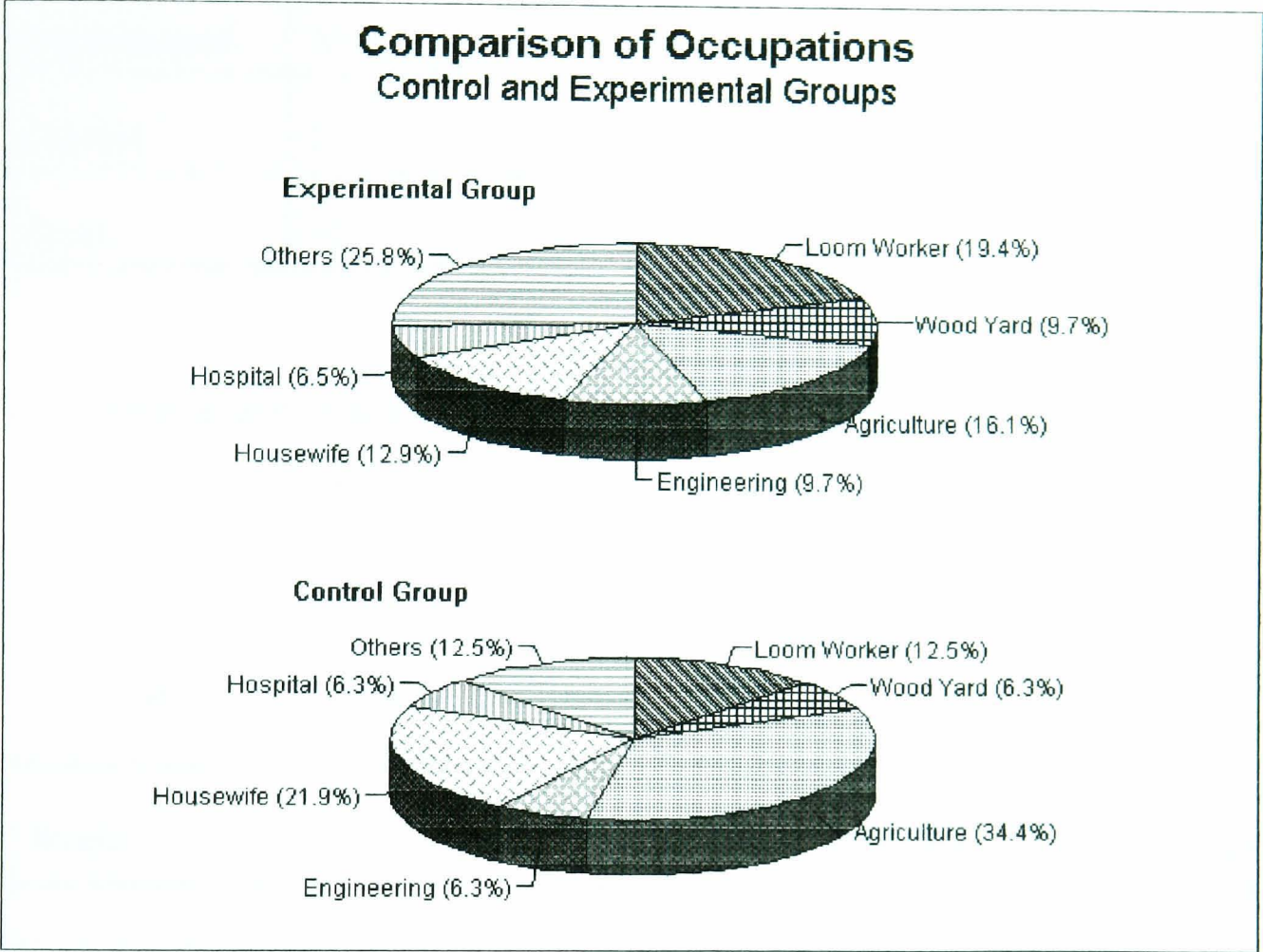


Perforation



Malignant proliferation

Figure 11



Fisher's Exact Test

Occupation	χ^2
Loom worker	0.34 NS
Agriculture	1.34 NS
Wood yard	0.18 NS
Engineering	0.18 NS
Housewife	0.69 NS
Hospital	No Difference
Other	1.12 NS

Table 6: Leprosy Classification (Ridley Jopling see Section 2.1.4.)

Group	BT	BL	LL	Total
Experimental	20	5	6	31
Control	17	7	7	31
Total	37	7	7	31

5. Comparison of disease types between groups $\chi^2 = 0.65$ 2df NS

Table 7: Index of Deformity

Grade	Deformity	Experimental	Control	Total
Grade 1	Anaesthesia only			
Grade 2	Loss of lesser toes or digital function	17	14	31
Grade 3	Loss of hallux or hallux function	8	8	16
Grade 4	Reabsorbtion or partial reabsorbtion of more than one metatarsal head.	5	8	13
Grade 5	Short foot	5	5	10
	Total	35	35	70

6. Comparison of deformities between groups : $\chi^2 = 0.98$ 3df NS

Table 8: Sites of Ulceration

Site	Experimental	Control	Total
1st. MTH* ¹	15	13	27
2 or 3 MTH	15	12	27
4 or 5 MTH	4	7	11
Others* ²	6	7	14
Total	40	39	79

*¹ Metatarsal Head

*² Ulcers categorised as "Others" included:

	<u>Experimental</u>	<u>Control</u>
Heel	2	2
Digital	1	1
Mid Foot	2	4
Hallux	1	0

7. Comparison of ulcer sites between groups: $\chi^2 = 1.35$ 3df NS

Morphology Of Ulceration

Table 9: Ulcer Edges

Type	Undermined	Indurated	Shelved*	Total
Experimental	20	15	5	40
Control	25	11	3	39
Total	45	26	8	79
χ^2	1.60 / NS	0.77 / NS	0.5 / NS	

Table 10: Ulcer Surfaces

Type	Slough	Granulation	Perforating*	Total
Experimental	12	20	8	40
Control	13	21	5	39
Total	25	41	12	79
χ^2	0.15 / NS	0.12 / NS	.74 / NS	

*The Fisher-Irwin Exact Test was used to compare groups where observed frequencies were less than five.

8. Comparison of morphological indicators between groups P < 0.05 NS

9. Comparison of ulcer area between groups (see Figure 12)
(Mann-Whitney U test)

Control Group	n=39		
Experimental Group	n=40		
Medians	Control Group = 1.57	Experimental Group = 1.85	
U=758 'U' = 782.5	95%CI = -0.39 to 0.39	NS	

Having compared the sample details of the Experimental and Control groups, it was found that the two groups were similar. There were more agricultural workers in the Control group than in the Experimental group. However when these two sub groups were compared as proportions of the the groups they represented, the difference was not found to be significant.

Analysis of the data collected in July established that the groups were homogenous at the onset of the trial. The data relating to ulceration, recorded at subsequent assessments, was compared to identify changes in characteristics.

Figure 12

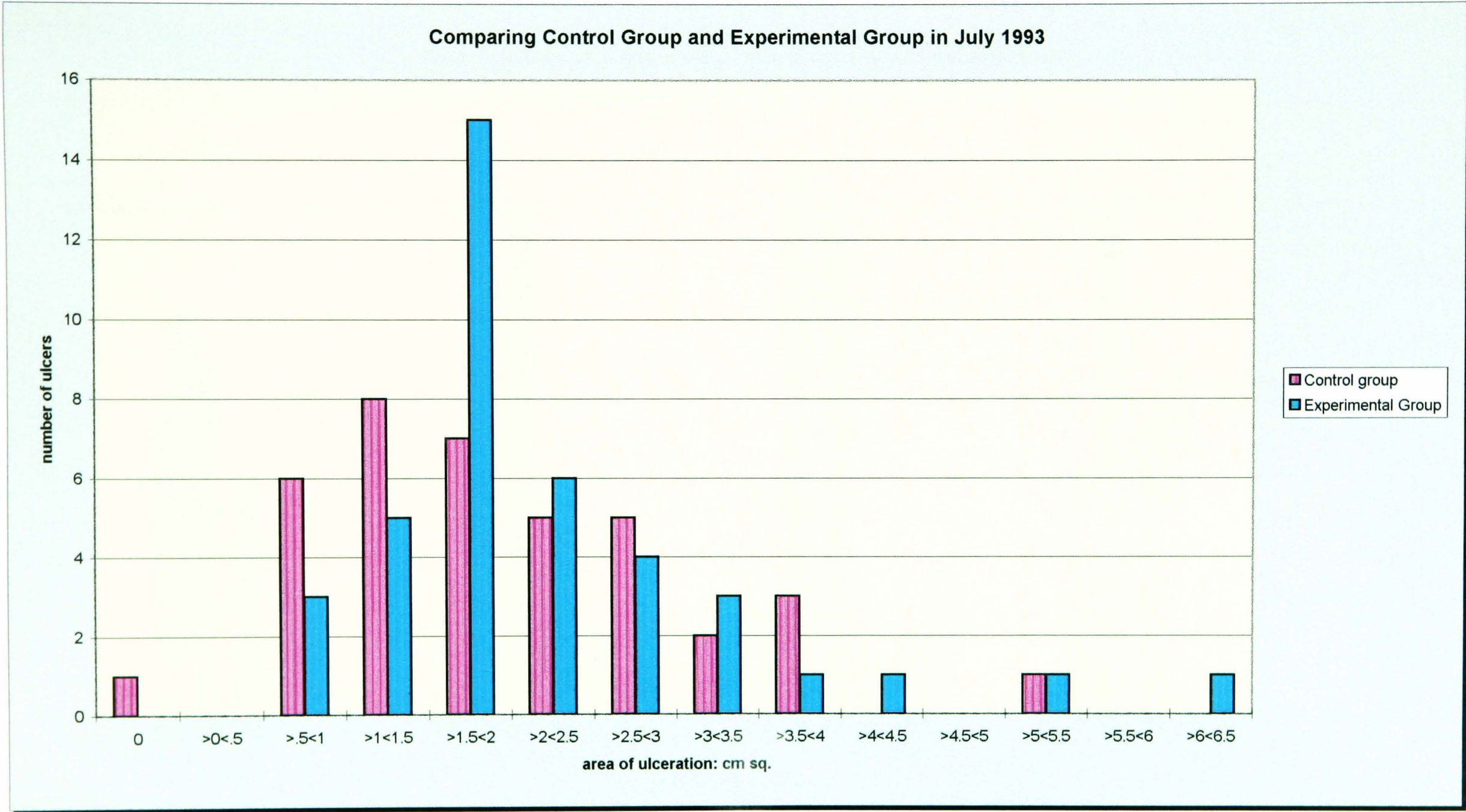


Figure 13

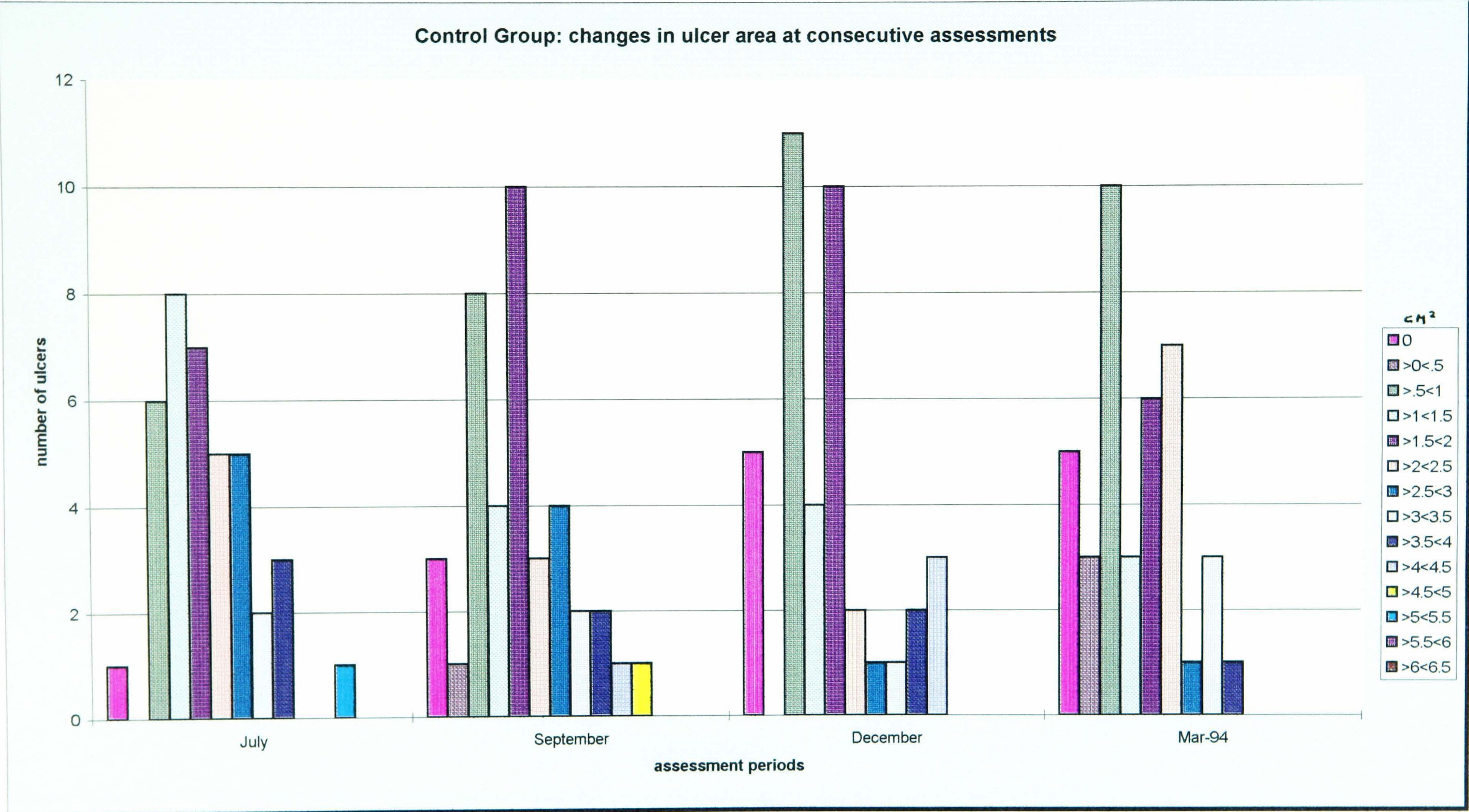


Figure 14

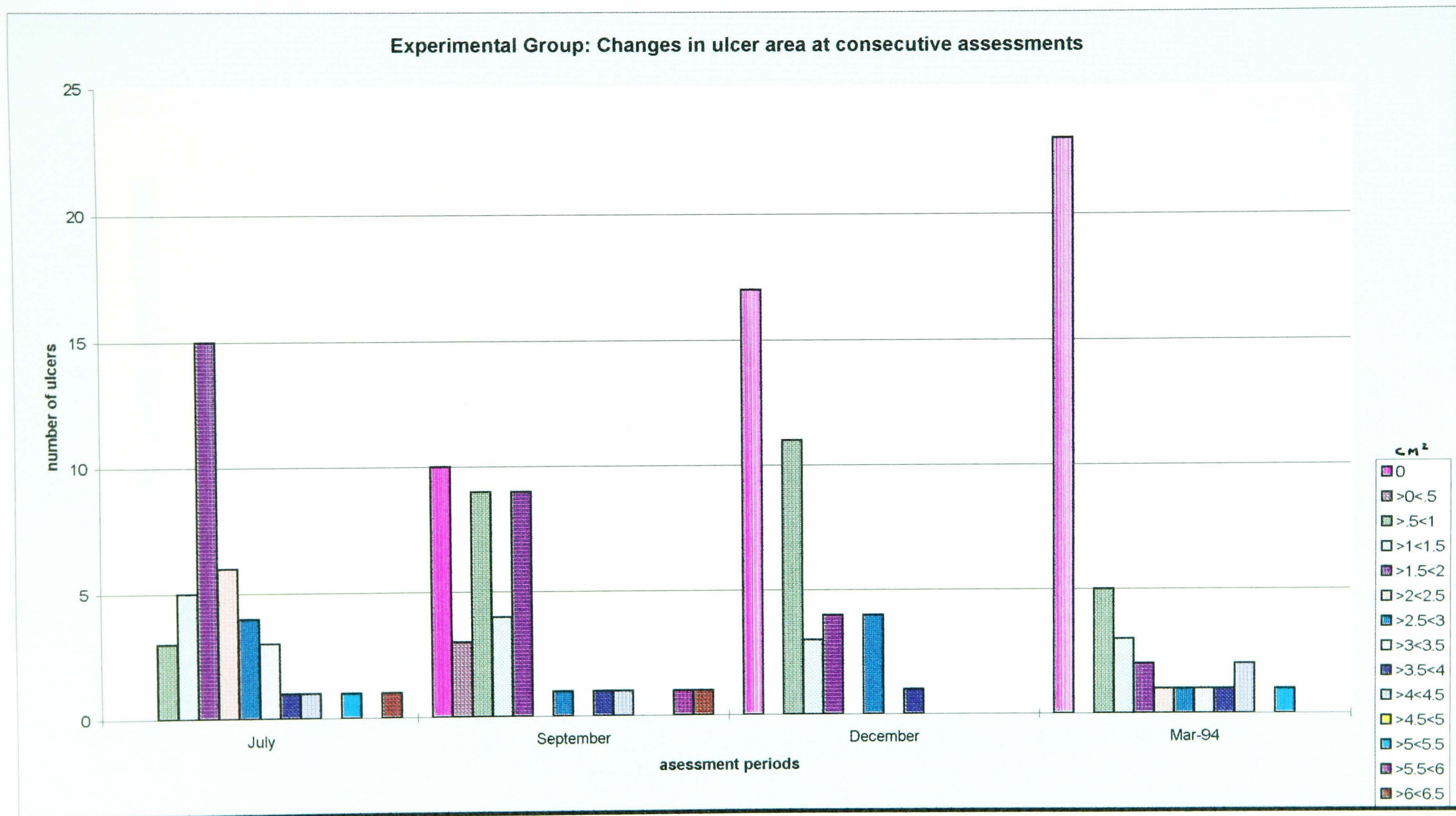
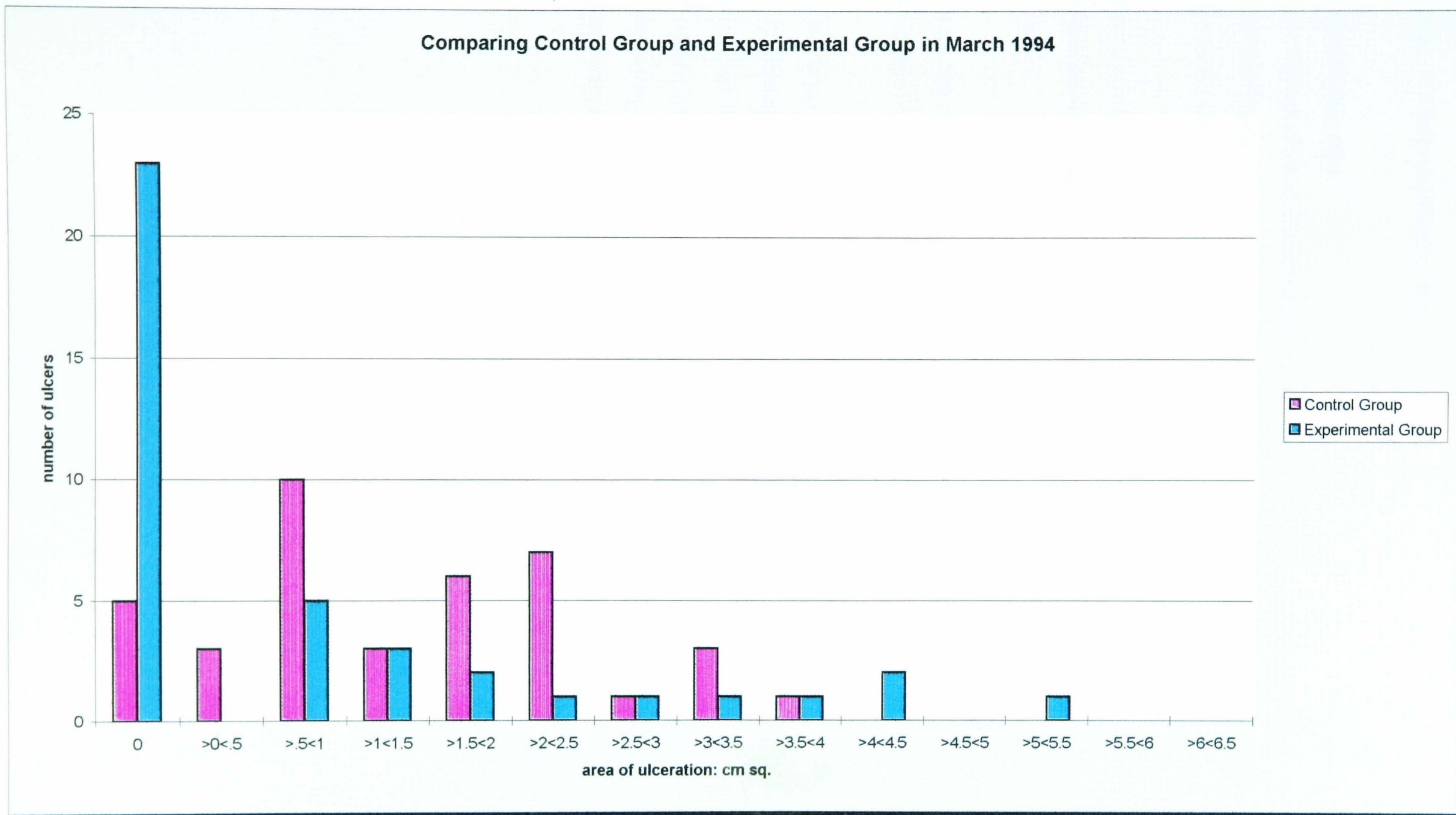


Figure 15



2.3.2 COMPARISONS: MARCH 1994

Test 1: Ulcer area

Data relating to ulcer areas recorded during the March 1994 assessment of the **Control Group** were compared with those of the **Experimental Group** recorded during the same period (see Fig. 15).

Control Group ulcers	n = 39	
Experimental Group ulcers	n = 40	
Medians	Control Group = 1.18cm ²	Experimental Group = 0cm ²

Mann-Whitney U Test

U= 1089 U'= 451.5 95% CI .2 to 1.18 **P=0.0009**

In the **Experimental Group**, of **40** ulcers **23 (57.5%)** had healed.

In the **Control Group**, of **39** ulcers **5 (12.5%)** had healed.

The results demonstrate that a highly significant reduction in the mean area of ulceration was demonstrated between the two groups in March. This reduction is explained by the five fold number of healed ulcers in the Experimental group when compared with the Control Group.

Test 2: The relationship between ulcer morphology and changes in ulcer area

It was hypothesised that, as ulcer area diminished, the walls and surfaces of such ulcers would present with features considered to be characteristic of resolution. By way of example; upgrading from an indolent stage, with characteristic indurated edges and a sloughing surface, it would be expected that an ulcer would progress through a phase demonstrating granulation at the floor of the ulcer with gradual epithelialisation (shelved edges). Correspondingly, negative features would characterise ulcers that were increasing in area (eg undermined edges and a sloughing surface), or had become indolent (eg indurated edges and adherent slough). The inter-rater reliability of morphology classification was tested during the assessment procedure in September 1993 (See Appendix 1). For discussion on the validity of the method please see section 2.3.5.

Categorisation of Morphology:

Data describing morphology at successive assessments were categorised as **Regressive, Static and Progressive**.

If ulcers presented with undermined edges they were categorised as **Regressive** regardless of the surface floor. If ulcers presented with indurated edges but perforating or hypergranulating or malignant surfaces they were also categorised as **Regressive**.

If ulcers presented with indurated edges with sloughing or granulating surfaces they were categorised as **Static**.

If ulcers presented with shelved edges and granulation tissue they were categorised as **Progressive**.

Categorisation of Changes in Area

Data describing area of ulceration recorded in September 1993, December 1993 and March 1994 were also categorised as **Regressive**, **Static** and **Progressive**. If an ulcer was recorded as presenting with an area smaller than the previous assessment it was categorised as **Progressive**. Ulcers that had not changed in area, or had increased in area, were categorised as **Static** or **Regressive** respectively.

Categories were subsequently coded for analysis:

Progressive was coded **1**

Static was coded **2**

Regressive was coded **3**

Spearman's Rank Correlation was used to test for relationships between morphology and area within groups at each assessment.

Table 11: Spearman's Rank Correlation: The Relationship Between Ulcer Area and Morphology

Group	September 1993	December 1993	March 1994
Experimental	n = 40 r = 0.5 P = 0.001	n = 40 r = 0.2 P = 0.20	n = 40 r = 0.23 P = 0.3
Control	n = 39 r = 0.12 P = 0.3	n = 39 r = 0.23 P = 0.10	n = 39 r = 0.41 P = 0.01

Only 2 tests suggested relationships significantly different from no relationship (Experimental Group in September and Control Group in March). The relationships suggested between the variables on these occasions was weak.

This analysis indicates that if changes in ulcer area suggest resolution or regression the morphological changes that were recorded do not augment such findings. The more subjective method of assessment is not considered a valid instrument to measure changes in ulceration for this study. This issue is discussed later.

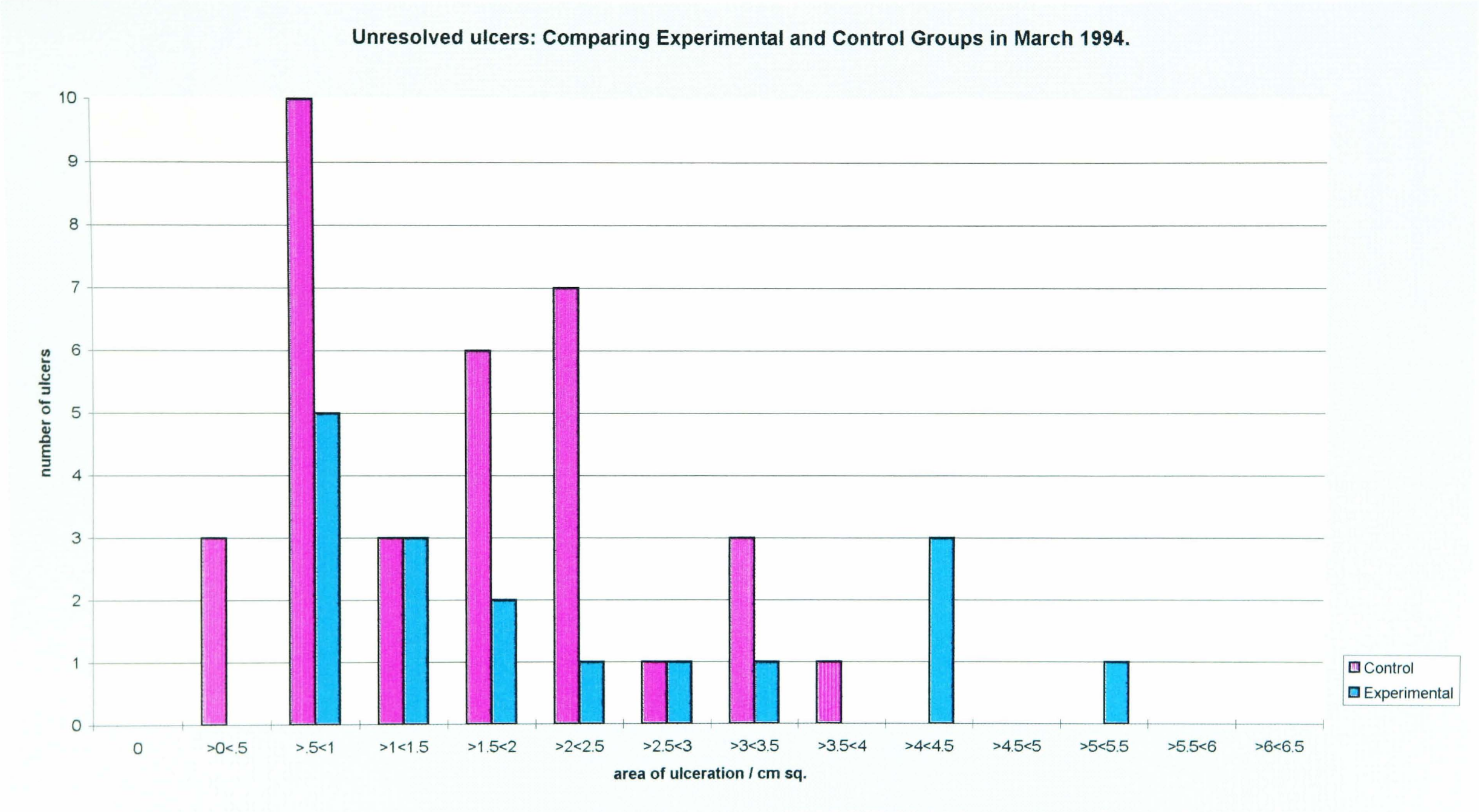
Test 3: Comparison of areas of unresolved ulcers between Control and Experimental sub groups

The author sought to establish whether the areas of **unresolved ulceration**, presented by Experimental group in March 1994, were smaller than those presented by the Control group. A positive indication would suggest that even though ulcers had not healed, experimental group subjects were still gaining benefit from the orthoses.

There were 17 subjects in the experimental group who presented with unresolved ulcers. The mean area of ulceration for this group was 2.94 cm^2 (STD = 1.4). 34 control group subjects presented with unresolved ulceration with a mean area of 1.6 cm^2 (STD = .90). Because the Experimental group sample was small ($n = 17$) the data were easily skewed by 4 outliers presenting with large areas of ulceration. This is demonstrated in Fig. 16.

Figure 16

Unresolved ulcers: Comparing Experimental and Control Groups in March 1994.



Test 4: Comparison of Experimental and Control sub groups on *the area of unresolved ulcers* in March 1994.

Control Group	n = 34	
Experimental Group	n = 17	
Medians	Control Group = 1.57cm ²	Experimental Group = 1.57cm ²

Mann-Whitney U Test

U=337.5 'U'=96 95% CI = .02 to 1.18 **N.S.**

This analysis does not support the hypothesis that the orthoses also benefitted those in the experimental group who presented with unresolved ulcers. An alternative hypothesis was that other variables may have confounded the orthotic effects for subjects with unresolved ulcers. It was imperative, therefore, to conduct further tests to identify extraneous variables.

Test 5: A within group comparison of unresolved ulcers

I sought to establish whether there had been a significant decrease in the area of unresolved ulceration by March. If the Control group subjects demonstrated a significant decrease but the Experimental group subjects did not, an implication may be that, for some subjects, the orthoses may have had an inhibitory or counteractive effect.

Data describing ulcers that were not resolved by March 1994 were compared with data relating to the same ulcers recorded in July 1993 (see Fig 17).

Control Group	Unresolved ulcers	n=34
Medians:	July = 2cm ²	March = 1.57cm ²

Wilcoxon Signed Ranks Test

95% CI=.1 to .985 **One Tailed P=0.01**

Figure 17

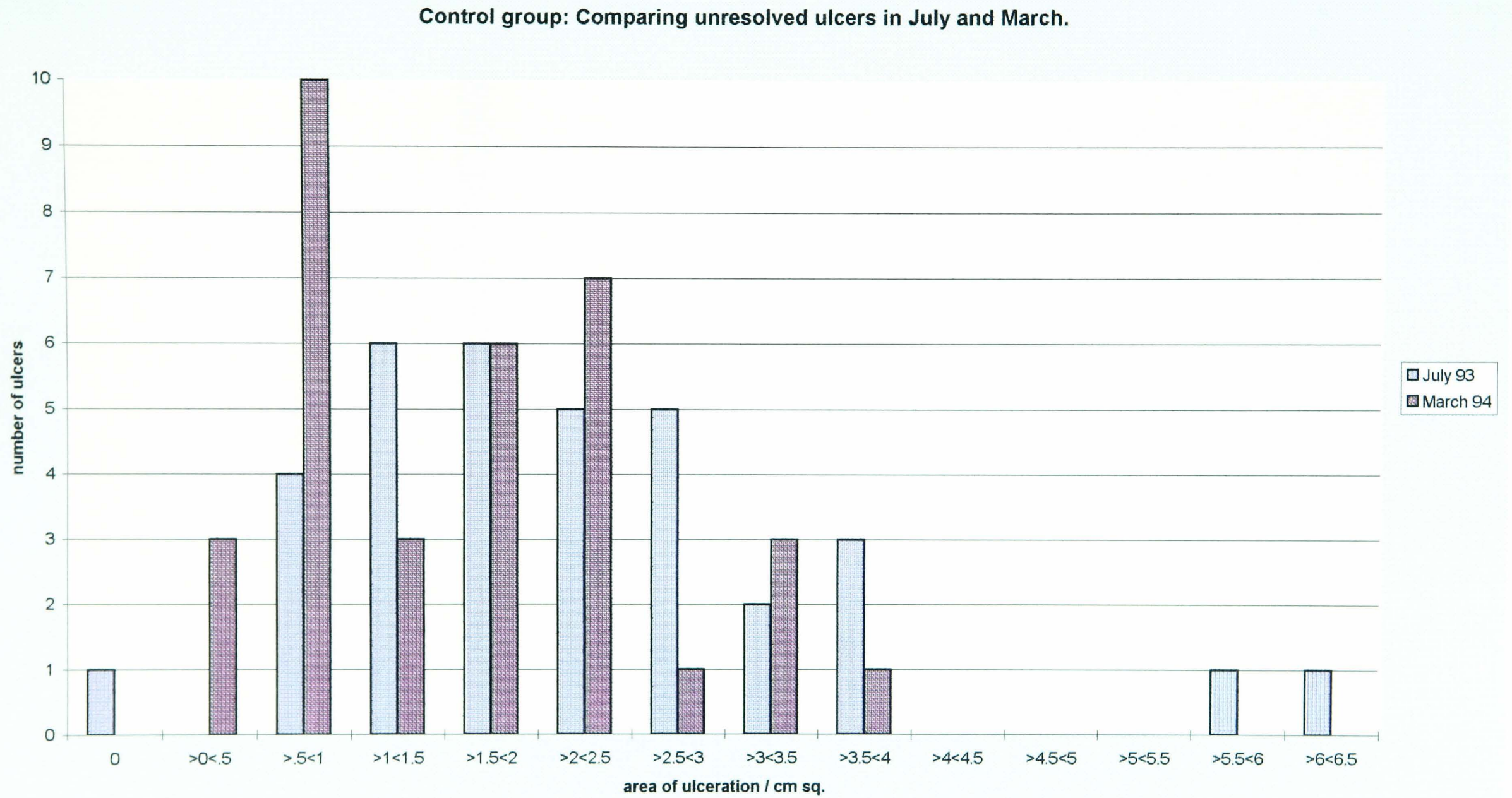
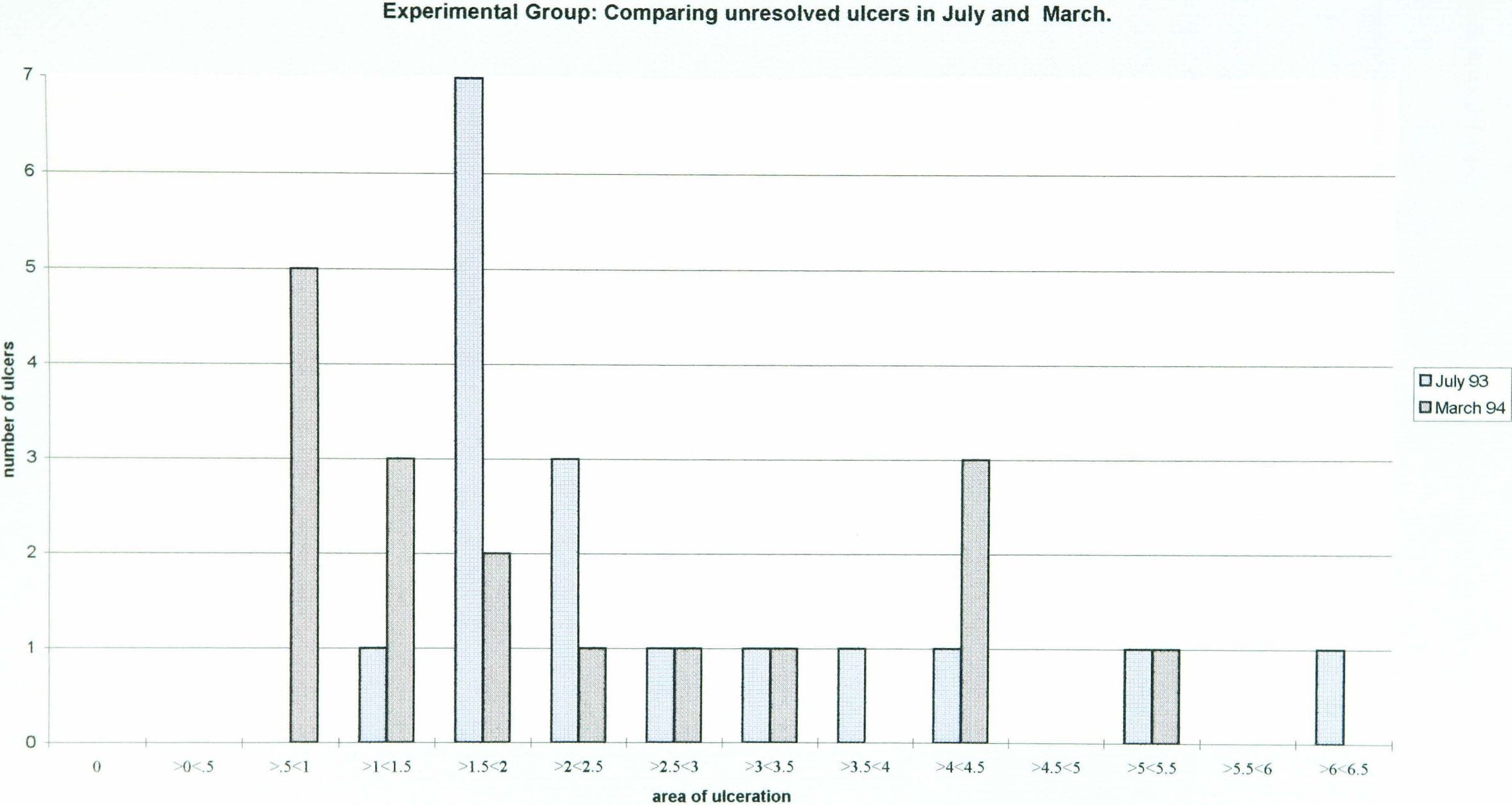


Figure 18



Experimental Group Unresolved ulcers: n = 17 (see Fig 18)

Medians: July = 2.36 March = 1.57

Wilcoxon Signed Ranks Test

95% CI= 0 to 1.08 **One Tailed P=0.04**

The findings suggest that the improvements in both groups were significant. The gradual trend towards resolution in the Control Group was similar to that in the Experimental group. An implication of this observation is that the orthoses, worn by experimental group subjects with unresolved ulcers, appear not to have disadvantaged the subjects. Clearly, some other variable(s) confounded ulcer resolution amongst this group. This investigation was therefore extended to examine independent variables with the intention of identifying potentially confounding variables.

2.3.3 Investigations of the effects of independent variables

Redefinition of the dependent variable

An aim of the preceding analysis was to describe the effects of orthoses on ulcers. It was expedient therefore that the areas of individual ulcers were considered. The investigation continued by examining variables that may affect resolution or regression independent of the effects of the orthoses.

In redefining the parameters there was an issue to resolve. Some feet presented with multiple ulcers (Experimental Group n=4, Control Group n=4). Furthermore, one of these feet demonstrated that individual ulcers, on the same foot, responded to treatment differently (i.e. whilst one ulcer was resolving another was regressing). This situation would have been problematic when investigating some variables that are unlikely to affect individual ulcers independently (eg. seasonal variations in climate). To resolve this dilemma the dependent variable was redefined and is henceforth the **area of ulceration on a foot**. Where a foot presented with multiple ulcers, the sum of individual areas of ulceration represented the dependent variable. Changes in the aggregate area of ulceration, at successive assessments, were considered indications of resolution or regression for the foot. The emphasis was moved from focus on the lesion to focus on the traumatised foot.

Test 6: The effect of initial ulcer area as an independent variable.

This investigation considered the initial **area of ulceration** at the onset of the programme. Three subgroups, **Healed**, **Resolving** and **Regressing** were defined and a pattern of healing rates was charted. These data were compared using Kruskal-Wallis test to describe the independent effects of initial ulcer area.

Experimental Group

Each group was divided into three subgroups:

Healed represents feet that had healed by March 1994.

Resolving represents feet that demonstrated a progressive reduction in area of ulceration from July/August 1993 to March 1994.

Regressing represents feet that had demonstrated a progressive reduction in area of ulceration from July/August 1993 to December 1993. At the March 1994 assessment these ulcers were recorded as presenting with no change in area or a greater area than that recorded in December 1993.

Table 12: Mean Area of Ulceration: Control Sub Groups

Sub Group	July/Aug 93	Sept. 93	Dec. 93	March 94
Healed n=5	1.10cm ²	0.71cm ²	0.31cm ²	0.00
Resolving n=13	3.07 ²	2.79cm ²	2.96cm ²	1.57cm ²
Regressing n=17	2.05cm ²	1.70cm ²	1.40cm ²	2.00cm ²

(see Fig 19)

Table 13: Mean Area of Ulceration: Experimental Sub Groups

Sub Group	July/Aug 93	Sept. 93	Dec. 93	March 94
Healed n=18	1.95cm ²	0.65cm ²	0.26cm ²	0.00
Resolving n=6	2.68cm ²	2.03cm ²	2.09cm ²	1.01cm ²
Regressing n=11	3.30cm ²	2.57cm.	1.53cm ²	2.82cm ²

(see Fig 20)

Figure 19

Three Control Group Sub groups

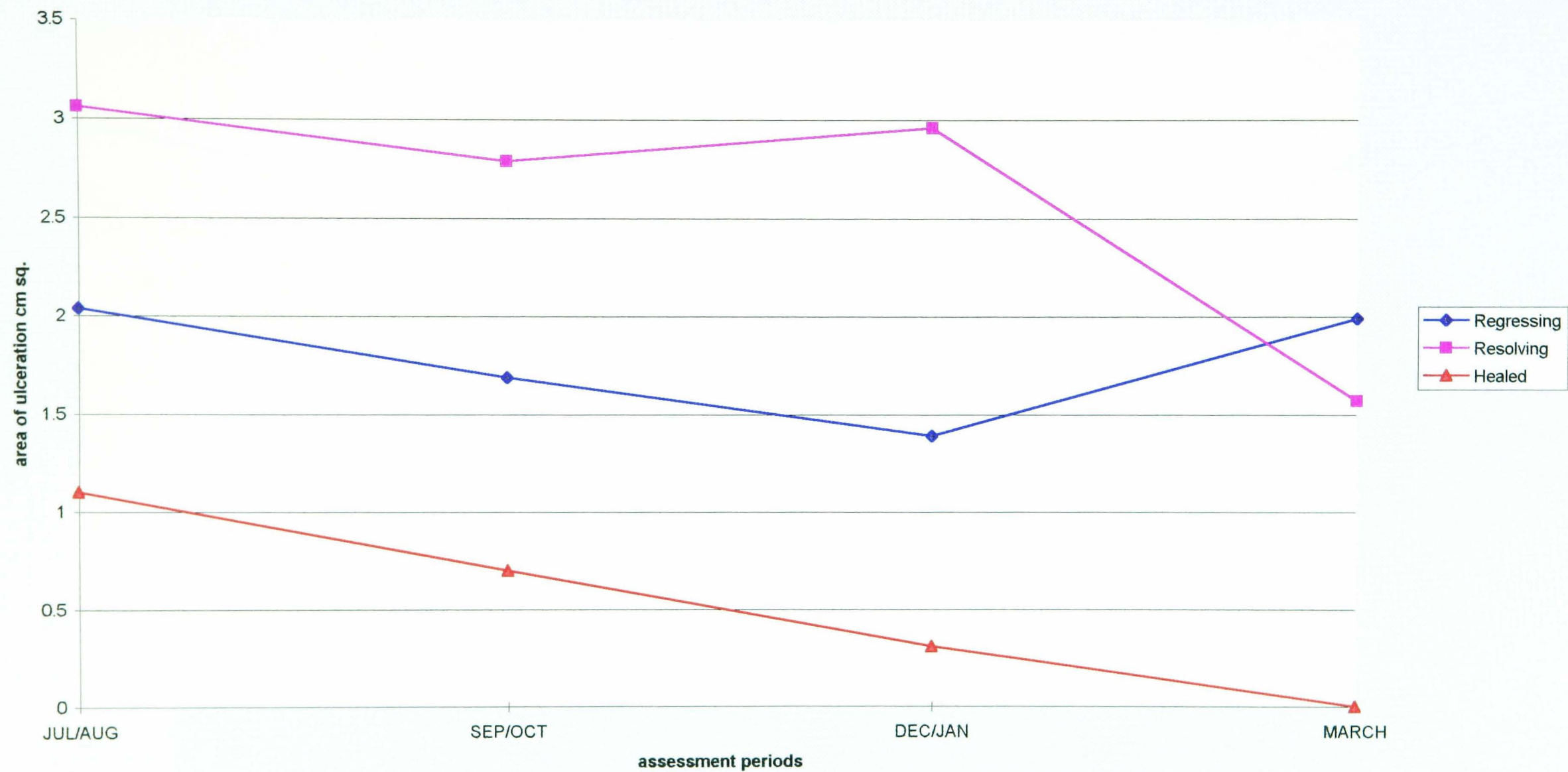
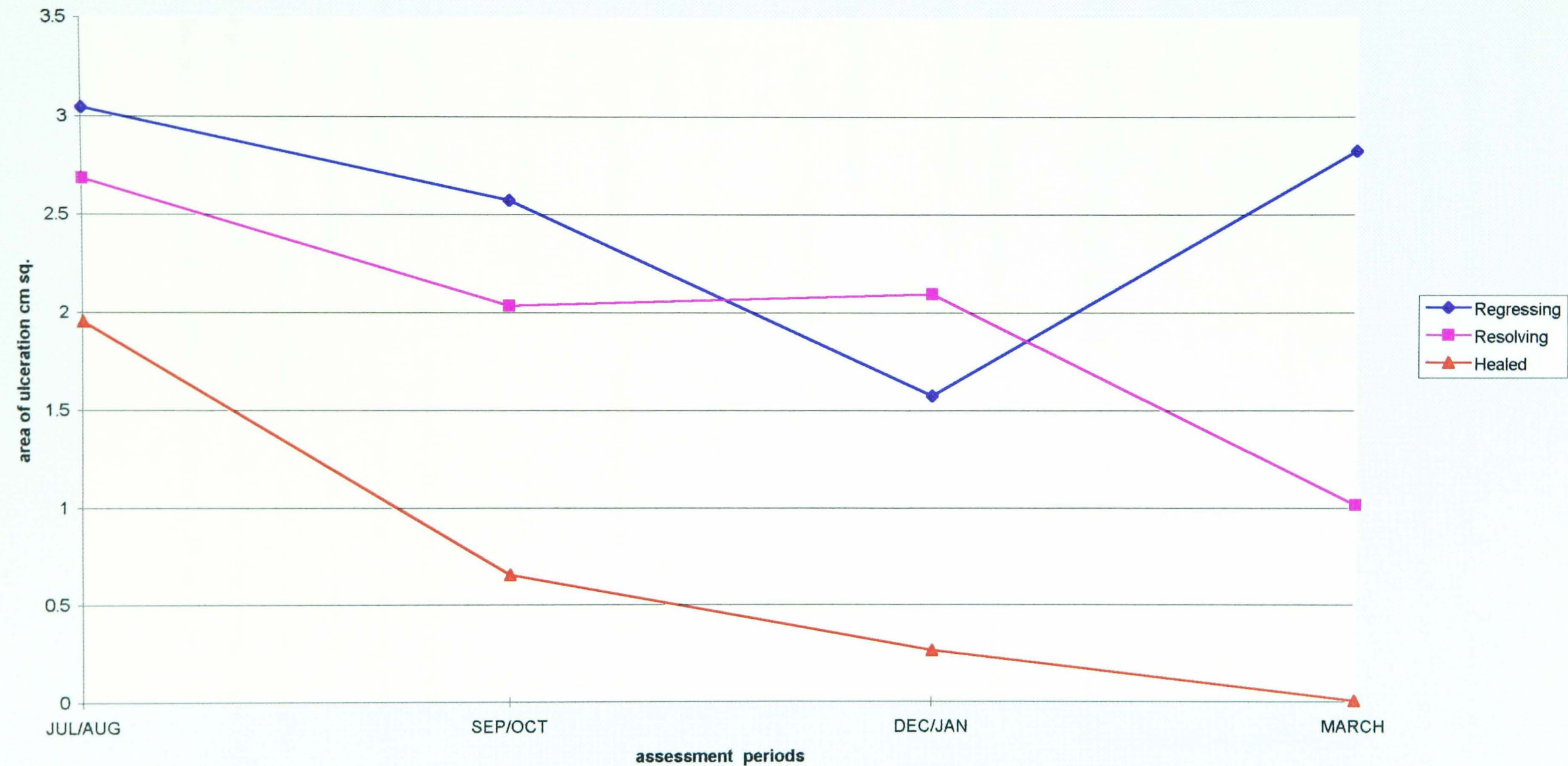


Figure 20

Three Experimental Sub Groups



Kruskal - Wallis Test

Table 14: Comparing Area of "Healed", "Resolving" and "Regressing" Sub Groups
From the Experimental and Control Groups Respectively: 2df $\alpha = 0.05$

	Experimental Group	Control Group
July	T=5.02 P=0.08	T=9.66 P=0.01
September	T=11.35 P=0.003	T=10.90 P=0.004
December	T=21.44 P<0.001	T=17.28 P=0.0002

Mann Whitney "U" Test for comparisons between area of **Regressing** and **Resolving** groups in March 1994

Experimental Sub Groups

Medians: **Regressing** = 2.82 **Resolving** = 0.9
U = 8 U' = 49
95% CI .3.33 to 0.3 **P=0.002**

Control Sub Groups

Medians: **Regressing** = 1.77 **Resolving** = 1.18
U = 81 U' = 114
95% CI -1.18 to 0.39 **P = 0.39**

The issue of interest in this analysis is ulcer regression and the identification of variables associated with it. The author had considered that the area of ulceration, at the first assessment, may have been a confounding variable. Area may have determined whether the site of interest was likely to demonstrate regression within the period of interest. If this could be demonstrated then it may be possible to identify ulcers with dimensions that would be too large to be treated with orthoses.

Feet in the **Experimental** sub groups defined as **Regressing** and **Healed** presented ulcers displaying mean areas of 3.30cms^2 (STD 1.94) and 1.95cms^2 (STD = 0.72) respectively, at the initial assessment. The difference in dimensions between **Regressing** and **Healed** feet which approached significance at the July assessment was shown to increase at subsequent assessments. However, the ulcerated feet in the **Regressing** group did demonstrate a linear time/area reduction approximating that of healed ulcers until December 1993. This suggests that there may have been a time/area dependency affecting the regression of ulceration.

Ulcers with a larger area at the start of intervention may not have had sufficient time to resolve before the orthoses had lost their integrity. This factor, or some other treatment related effect, may have confounded further resolution. However, why this should have affected some subjects and not others needs further explanation. Field records suggest that subjects were well monitored during this period and recourse will be made to these records to elucidate this issue.

There are, however, indications in the **Control subgroup** findings which should also be considered. Feet in the **Control subgroup** defined as **Resolving** presented with initial areas of ulceration that were significantly larger than areas in the subgroup **Regressing**. This finding opposes the hypothesis that initial ulcer area will determine whether ulcers regress.

Explanations arising from subject files and field notes.

By December 1993 the mean area of ulceration recorded for the **Experimental** Group defined as **Regressing** had decreased to 1.53cms^2 . The mean area of ulceration recorded in March was 2.82cms^2 (STD 1.44cms). Recourse to field records disclosed that three Subjects from this group had lost their orthoses between January and March. All other orthoses in this group required repair.

Of the group defined as **Resolving** (n=6) 3 subjects had lost or discontinued use of their devices for periods ranging from two weeks to one month in the period between September and December. One other subject in the group required major repair to his device. Another subject from this group had discontinued the use of his orthosis for a one month period. It was recorded that he presented with an increase of 2cm² in ulcer area at the December assessment. The subjects that were without devices for a shorter time span were not recorded as presenting with a greater area of ulceration in December.

A large increase in ulcer area (1.18cm²) over the September to December period was presented by a subject in the **Resolving** subgroup. He is a security guard who responded to a late night robbery by pursuing the gangsters barefoot. (It was the regression of these two ulcers that explain the increase in mean area for the group **Resolving** recorded in December.)

In March, all remaining subjects with healed ulcers presented devices that were in reasonable condition. Most devices required a renewed application of adhesive or refitting into new sandals or other footwear.

2.3.4 INVESTIGATION OF FURTHER INDEPENDENT VARIABLES

The author sought to investigate whether there were other variables that may have affected ulcer resolution amongst subjects in the Experimental group.

Deformity

When designing a classification model for deformities the rationale in so doing was that it was considered that feet with grade 5 deformities would be more compromised than feet with grade 1 deformities (see Fig.9). Two subgroups were compared on the variable of deformity to establish whether regression of ulceration may have been dependent on deformity. The hypothesis was that subjects with more deformed feet were more likely to demonstrate regression.

For this test, subjects from the subgroup **Regressing** were compared with a subgroup comprising all other subjects. **Regressing** represents Experimental group feet that presented with ulceration that increased in area between December 1993 and March 1994. **Others** represents a combination of the sub groups previously defined as **Resolving** and **Healed**. The areas of ulceration presented by samples combined to form this group were not found to be significantly different in dimension whereas **Healed** and **Regressing** ulcers were. **Resolving** and **Regressing** ulcers were found to be significantly different at the July and March assessments.

A limitation of the analysis is that the groups for comparison are small. Even though data were collapsed there were still insufficient numbers to justify the χ^2 test for subjects with greater deformities. The Fisher-Irwin exact test was used for the smaller group. A further limitation is that subjects with more severe deformities are only more disadvantaged if all other variables are similar. It may be that those with more severe deformities are less mobile, in which case they may not be more compromised.

Accepting these limitations, analysis of the data indicated that there were no significant differences between the group defined as **Regressing** and that defined as **Others** (see Table 15).

Table 15: Comparison of Deformities Presented by Experimental Sub Groups

	Regression		Total
	Yes	No	
Grade 2 and 3	7	18	25
Grade 4 and 5	4	6	10
Total	11	24	35

Fisher-Irwin Exact Test $\chi^2 = 0.47$ **P = 0.48**

Site of Ulceration

A further consideration was that some subjects may have been advantaged if they presented with ulceration at sites that would more readily respond to treatment. It was hypothesised that medial ulcers (Hallux and MTH 1, 2 and 3) were more likely to regress than lateral ulcers (MTH 3,4 and 5). This theory was based on an assumption that a majority of medial ulcers were related to forefoot hypermobility and first ray incompetence. These defects require an approach that controls and/or moderates foot function as opposed to defects responsible for lateral ulceration which require the palliation of foot function. The author considered that addressing foot function may be more problematic than palliation.

As with the preceding analysis this examination is limited by sample size. Only forefoot sites were compared. 2 heel ulcers in the group defined as **Regressing** were excluded, as were 1 digital ulcer and 2 midfoot ulcers in the group defined as **Other**. Data were collapsed to facilitate the Fisher-Irwin Test. The difference between the groups was not found to be significant (see Table 16).

Table 16: Comparing Sites of Ulceration on Evidence of Ulcer Regression

	Regression		Total
	Yes	No	
Medial ulcers	7	20	27
Lateral ulcers	3	5	8
Total	10	25	35

Fisher-Irwin Exact Test $\chi^2 = 0.40$ P = 0.52

A null hypothesis that medial ulcers were less likely to regress than lateral ulcers was, therefore, not supported. However it is reiterated that the sample of lateral ulcers was small and consequently significance would be more difficult to demonstrate. Accepting this limitation, the findings suggest that ulcer site is an extraneous variable that did not affect the course of healing or regression.

Footwear

A further consideration was that the type of footwear worn by individuals in alternative groups may have confounded results.

Footwear: Regressing (n = 11)

One subject was recorded as wearing plastic shoes, another wore sandals from a local market, all other subjects wore Micro cellular rubber (M.C.R.) sandals made at Dr Bandorawalla Leprosy Hospital.

Footwear: Others (n = 24)

Two subjects were recorded as wearing plastic shoes, two other subjects wore trainers, all other subjects wore Micro cellular rubber sandals made at Dr Bandorawalla Leprosy Hospital.

Table 17: Comparison of Footwear Presented by Experimental Sub Groups

	Foot Wear		Total
	M.C.R. Sandals	Market Foot Wear	
Regressing	9	2	11
Others	20	4	24
Total	29	6	35

Fisher-Irwin Exact Test $\chi^2 = 0.01$ P = 0.91

81% and 83% of subjects in the **Regressing** and **Other** groups respectively wore M.C.R. sandals. There was no significant difference between the groups on the variable of footwear.

2.3.5 SUMMARY OF RESULTS

The results that have been presented indicate that after a six month period subjects in the Experimental group were more likely to present with healed ulcers (52%) than subjects in the Control group (12%). This was a compelling result demonstrating that ulceration can be addressed more successfully with orthoses than without. On the strength of these results, it was hypothesised that subjects in the Experimental group with unresolved ulcers in March 1994 would still have benefited by wearing orthoses. Support for this hypothesis required evidence that experimental group ulcers that had not healed presented with smaller areas of ulceration than control group ulcers. What transpired was that unhealed Experimental group ulcers were not significantly different from Control group unresolved ulcers when compared on ulcer area. It was noted, however, that the Experimental group sample size was small and results were easily skewed by outliers presenting with large areas of ulceration. It was hoped that should such findings be made they may have been elucidated by considering data relating to the morphology of ulceration.

An aim was to establish whether morphological changes, associated with ulcer resolution or regression, could be assessed and recorded simultaneously with ulcer dimensions. Had this been a valid form of measurement it would have augmented findings, particularly where unhealed ulcers required comparison. It was found, however, that when data were categorised and Spearman's rank correlation coefficient was applied, there was no correlation between the variables. The conclusion drawn from this finding was that if changes in ulcer area suggest resolution or regression the morphological changes that were recorded do not augment such findings. Since ulcer area is a clearer and more objective measurement, the more subjective categorisation of morphological observations was not considered a valid indicator. Further investigation therefore was reliant on observations relating to ulcer dimensions.

It had been noted that, although there was not a significant difference in the areas of ulceration between groups, 11 of the 17 Experimental group ulcers had demonstrated

an increase in ulcer area between December 1993 and March 1994. This required explanation and precipitated an investigation to identify independent variables that may be associated with ulcer regression.

The author postulated that the area of ulceration at the 1st assessment may have been a confounding variable. Ulcers with a larger area at the start of intervention may not have had sufficient time to resolve before orthoses had lost their integrity. However further study was required to investigate reasons why this had affected some subjects but not others. Recourse was made to field records and subjects' files to elucidate the findings. Of those ulcer sites recorded as regressing, 3 were presented by subjects who had lost their orthoses between January and March 1994. All other orthoses in this group required repair. Other subjects with ulcer sites recorded as "resolving" were also recorded as having lost or discontinued use of orthoses for varying periods between September and December. Being without orthoses for periods greater than two weeks did appear to account for an increase in ulcer area, as did poorly maintained devices. There was also evidence of idiosyncratic events that appear to explain sudden increases in ulcer area (eg. barefoot pursuit of robbers: see page 102).

When considering reasons for ulcer regression the above features are considered salient. However, they may not be independent of other variables. Studying the results relating to the Control group it became apparent that initial ulcer area may not be as critical as Experimental group findings suggested. Feet in the control group defined as "Resolving" presented with areas of ulceration that were initially significantly larger than areas in a subgroup defined as "Regressing". There were, furthermore, a significant number of subjects in the control group that experienced regression of ulceration between December 1993 and March 1994. (The same parameters were used to identify this group as were used to define the Experimental sub group.) These findings suggested that results may have been confounded by other variables.

The possibility of climate influencing healing is a possibility. It is the author's contention that the drought conditions that prevail in Maharashtra from December through March may exacerbate the inelasticity of skin primarily compromised by

autonomic loss. Alternatively, drought may be associated with modification of life style that may precipitate regression. Anecdotal evidence suggests that there is an exaggerated increase in the incidence of ulceration during the monsoon season (June to October). This may however be explained by an increase in the number of rural patients presenting for treatment during a period of reduced agricultural activity. The ulcerations in June may be the manifestation of trauma sustained during periods of pre Monsoon drought. Neither the effects of physical nor human geography have been pursued in this study, however the findings generate an interesting hypothesis that could be developed as an epidemiological study.

The potential for other variables to confound results was pursued. the author investigated whether foot deformity or the site of ulceration were variables that may have affected outcome. A difficulty encountered with this more detailed analysis was that the sample sizes were progressively smaller as parameters narrowed. It was found that deformity was not associated with regression. It is accepted that this may reflect a decreased activity level amongst those with more severe deformity and consequently less application of stress. However, accepting the limitations of sample size and the unresolved possibility of other secondary confounding variables, deformity appears not to have affected the results.

In section 2.3.3. an hypothesis was advanced suggesting that medial sites of ulceration were more likely to demonstrate regression than lateral sites. The rationale for this suggestion is based on the assumption that medial ulcers require orthoses that moderate functional effects, whilst lateral ulcers require palliation. The authors contention was, therefore, that medial ulcers would be more difficult to control. This rationale will be discussed in detail following this summary and will not be pursued further here. The findings did not support the hypothesis. Further investigation demonstrated that whilst Control group medial ulcers did appear to demonstrate regression, Experimental group medial ulcers demonstrated significantly different characteristics. This finding was interesting. It suggested that the problems associated with medial ulcers could be addressed in a sustainable manner. The control group findings generate further hypotheses suggesting, for example, that medial ulcers do

require a therapeutic approach that addresses more than the palliative effects of micro cellular rubber. As intimated above, associated issues will be discussed in detail later. A further variable merited consideration. Recourse to subject files was made to ascertain whether there may be an association between different styles of foot wear and ulcer regression. As with other variables sub group samples were very small. Accepting this limitation, it appears that ulcer regressions were not associated with different styles of foot wear.

2.4 DISCUSSION

Prior to this project, the effects of foot orthoses as a treatment, or adjunct to treatment for plantar ulceration in leprosy had not been investigated empirically. Brand (1991) has expressed reserve in his opinion of orthotic intervention for neuropathic feet. His concern was that improperly placed devices may increase focal pressures and exacerbate ulceration. Whilst recognising this hazard, the results of this study illustrate that orthotic intervention can significantly reduce the duration of ulceration. It is unfortunate that there is a paucity of clinical evidence to support the validity of foot orthotic intervention. The accessibility of technology has, however, facilitated studies to challenge many of the theories relating to pedal mechanics and their dependency on foot orthoses. Consideration of such studies does, in part, compensate for the lack of wider clinical evidence by establishing the construct validity of orthotic intervention.

2.4.1 THE EFFECTS OF INSHOE ORTHOSES ON FORCE RELATED PARAMETERS

Studies that have sought to examine the effects of inshoe appliances demonstrate two principle perspectives. Some have based their investigation on examining the effects of rearfoot control (Rose *et al.* 1992, Novick *et al.* 1993) whilst others have sought to examine the effects of palliative appliances or choice of material (Bradley and Balder 1986, Leber and Evanski 1986, Patil and Srinivassan 1987, Veves *et al.* 1989, Holmes and Timmerman 1990, Barrow *et al.* 1992, Lord and Hosien 1994, Chang *et al.* 1994, Hayda *et al.* 1994, McLaughlan *et al.* 1994). These investigators all measured kinetic variables.

The term "functional orthosis" is generally reserved for devices that control rearfoot kinematics and thereby alter the function of the entire foot. Palliative devices are considered to be more passive in effect, supporting problematic structural abnormalities. However the potential for palliative devices to affect function should not be discounted. Investigations ought, therefore, to consider whether an appliance

demonstrates an ability to redistribute force through the foot in an appropriate and controlled manner. Where this can be demonstrated it may be inferred that balance and function have been enhanced. Assuming these factors do predispose the foot to tissue stress, the control or moderation of function may also be assumed to reduce trauma. This may require accommodating fixed forefoot deformities, equalising limb length discrepancies or stabilising the foot against the effects of functional maladaptation. By so doing load transfer patterns should demonstrate deviations away from established patterns toward those of more normal loading patterns. A reduction in tissue stress may be anticipated where it is demonstrated that forces have been transferred from vulnerable areas to underused or tolerant areas. Reductions in shearing stress, compression (direct pressure), tension (related to impulse), and shock (impact) are further indications of reductions in stress.

Foot function varies considerably between individuals and should be considered as an independent variable. Although standardised principles may be applied to individuals, generalisations relating to the response of the foot to a standardised intervention are spurious. In neither the study of Holmes and Timmerman (1990) nor McLaughlin *et al.* (1994) was sufficient recognition given to the individuality of feet.

This omission may explain why Holmes and Timmerman (1990) were unable to record a significant reduction in pressure on the feet of male subjects wearing plantar pads. Male and female subjects were all given standard small metatarsal pads, the specifications of which were not described. That the devices may have been improperly positioned was discussed but the individual requirements for each subject was not considered.

The effects on peak pressure displayed by the use of an orthotic button compared with a metatarsal pad with a "U" cut to the second metatarsal head, was investigated by McLaughlin *et al.* (1994). They used piezoelectric transducers constructed from polyvinylidene fluoride film (The Gaitscan System). Their results indicated that the orthotic button significantly reduced peak pressures under all but the fifth metatarsal head. However, since the action of an orthotic button is to realign metatarsal shafts

and redistribute forefoot pressures more broadly, examination of loading patterns and/or time pressure integrals may have been more appropriate. High intra rater values indicated that the investigator's method of locating individual anatomical landmarks was reliable, thereby satisfying earlier criticism of palpation by Lord (1981). It is unfortunate therefore that McLaughlin *et al.* (1994) adopted standardised positions for the devices they used. As each subject was considered her/his own control and anatomical landmarks had been individually identified, more attention to placement may have resulted in more conclusive results. The metatarsal pad they used was found to reduce pressure only on the right second metatarsal head and was found not to have redistributed pressure significantly to the other metatarsal heads. As discussed earlier, peak pressure represents the centroid of pressure. When considering loading on the MTHs the entire area of interest should be considered.

Peak pressure may be a useful dependent variable to examine where the efficacy of an appliance is assessed by its ability to reduce, what has been identified as, a focal area of high pressure. This method was adopted by Barrow *et al.* (1992). They demonstrated a significant reduction in peak pressure that could be attributed a metatarsal pad with a "U" cut out to accommodate an area identified as demonstrating high peak pressures. In their study subjects presenting with abnormally high pressures on the second MTH were recruited. Dhanendran *et al.* (1980) who compared the effects of three different types of plantar metatarsal pads considered the effects of intervention on peak load. By covering or raising the MTHs the dissipation of force spatially or in time would affect pressure.

The choice of appropriate technology to measure the variables chosen is illustrated in the study conducted by Novick *et al.* (1993). They were able to record a significant reduction in vertical pressure on the first metatarsal head by using FSCAN (TEKSCAN INC. Boston MA.) and The Hercules System (ALLEGHENY BALLISTICS LAB. Cumberland, MD). Their objectives were to demonstrate the effects of 3 types of orthoses. Both systems produced generally the same pattern of findings although the magnitude of pressure values between the two systems is marked. This difference was explained as being due, possibly, to the more prominent

Hercules transducers resulting in a greater concentration of force over a relatively small surface area. The recognition that pressure is a function of force divided by area is also used to explain why the FSCAN transducer presented lower pressure readings. The identification of the required anatomical site by FSCAN software may have corresponded to a greater area onto which force was dispersed.

Studies of the orthotic effects on balance and control are enhanced by consideration of the trajectory of the C.o.P. Rose *et al.* (1992) also used the FSCAN system to study the effects of heel wedges on plantar pressures in asymptomatic feet. Their study contributes little toward the understanding of foot function due to omissions of fundamental biomechanical criteria in the design of their experiment. Their results are unremarkable but support intuitive understanding relating to the displacement of pressure and the centre of force medially with lateral wedging and laterally with medial wedging. However, extrapolation of their results may be used to illustrate some of the effects of poor footwear characterised by badly worn heels. The possible effects of poorly designed sandals, where the heel is found to be displaced medially, or laterally, may also be reflected by their findings.

2.4.1.1 Limitations in the literature

It was suggested earlier that events at the foot/ground interface should not be interpreted as representing events at the foot/shoe interface. Even where other relevant parameters have been identified and variables have otherwise been controlled clinical application is limited where studies have not considered inshoe conditions. Further criticism is that most of the studies reviewed here were cross sectional studies. The effects of time and force related variables on the materials used may significantly affect the therapeutic efficacy of appliances. The mechanical behaviour of materials used is fundamental to the therapeutic rationale supporting orthotic prescription. Where material characteristics change as an expression of time and/or force, findings relating only to new materials are limited. The necessity of testing the mechanical properties of orthotic materials over time is evident from the studies of Rome (Rome 1991, Edwards and Rome 1992) and Campbell *et al.* (1980). It has

been demonstrated that compression set and creep have altered the characteristics of materials in common use after a period of days. Barrow *et al.* (1992) demonstrated that the pressure relieving properties of a latex sponge button initially enhanced the effect of a plantar metatarsal pad. The appliance incorporated a "U" cut out for pressure deflection. The button was inserted into the cut out, presumably, to cushion impact. After a period of one month however, it appeared that the button exaggerated the effects of force.

2.4.2 CONJECTURED MECHANICAL EFFECTS

2.4.2.1 Tarsal cradles

Seventeen subjects were supplied with tarsal cradles that had been extended to incorporate cut away sections for pressure deflection. Two of these devices included a metatarsal bar as an alternative to a cut away section and 3 other devices included medial forefoot wedges. Of the 4 ulcers that did not heal in this group, one subject wore a tarsal cradle with a medial forefoot post. The other 3 subjects wore tarsal cradles that had been extended to incorporate cut away sections. The therapeutic rationale for prescribing a tarsal cradle was detailed in Section 2.1.10. It was suggested there, that the device has two primary actions. It acts as a substitute for the foot in its function of pressure accommodation and the redistribution of force. It also resists the effects and may reduce the extent of subtalar pronation. The benefit of this latter action is that it may contribute to the maintenance of the architecture and consequently the function of the foot. The significance of this hypothesis is expounded below.

By considering basic principles of engineering, Hicks (1953b) concluded that the effect of the medial arch was analogous with a beam effect. The analogy is that of a cross beam which is supported at both ends, with a load placed on its central aspect. As the beam bends, compression will increase within the top half of the beam whilst tension increases in the bottom half. The structure is stabilised by the plantar aponeurosis. Hicks likened the aponeurosis to a "tie rod" enabling the foot to bear

loads by a truss effect. An arch requires a horizontal force to act on the end supports of the structure in order to prevent the ends of the arch from spreading apart. The plantar aponeurosis was observed, by Hicks, to come under considerable tension during weight bearing. He reasoned that the restraining tension from the aponeurosis acted to prevent the arch from collapsing under load. Hicks developed the engineering analogy further to demonstrate the wider significance of the plantar aponeurosis. The aponeurosis has its origin at the medial tubercle of the calcaneus and inserts onto the bases of the proximal phalanges of the toes. Any action it may effect on the arch, therefore, will be reflected by concurrent action on the digits as well. During standing, the aponeurosis causes plantarflexion at the metatarsal phalangeal joints and contributes to the stabilisation of the kinematic chains of the digits and the metatarsophalangeal joints. The observed action on the digits could be attributed to the passive tension of the aponeurosis as it was reported that amputated specimens of feet demonstrated the same plantarflexion of digits. The implication is that the action could not have been attributed to muscle contraction.

Hicks' (1953b) recorded that by dorsiflexing the hallux, the arch of a load bearing foot could be raised. This observation led to the celebrated "Windlass Effect of Hicks" hypothesis. The medial bands of the aponeurosis are inserted onto the sesamoids and proximal phalanx of the hallux. When the hallux is dorsiflexed the resultant action is likened to that of a windlass in which a cable is wrapped around a cylinder by rotating the cylinder with a lever. In a similar manner the hallux is equated with a lever. With dorsiflexion of the hallux the aponeurosis is wound up distally and superiorly over the first metatarsal head. The inelasticity of the aponeurosis dictates that as it is drawn distally the calcaneus will dorsiflex and the first metatarsal will plantarflex. As a consequence of these events the arch will rise.

This mechanical model is "designed" to function within the parameters of normal phasic subtalar kinematics. Aphasic pronation is disruptive. With plantarflexion and eversion of the calcaneus the plantar fascia exerts an oblique pull on the proximal phalanges of the toes which destabilises the metatarsophalangeal joints. The hypermobility of the tarsals in response to talar adduction and plantarflexion leaves

the first metatarsal unstable. Further compromised by instability of the first metatarsophalangeal joint, the first metatarsal dorsiflexes in response to ground reaction. The plantar fascia, which under normal circumstances enhances stability, exerts an opposite effect to that of the windlass mechanism. The proximal phalanx of the hallux, being unable to dorsiflex adequately over the elevated first metatarsal head, impacts against it in response to the tensile force of the fascia. As a consequence the distal phalanx of the hallux must dorsiflex to accommodate propulsion. This results in excessive compressional stress in the tissues beneath the proximal phalanx whilst the unstable first metatarsal allows excessive shearing stress beneath the metatarsal head (see section 2.1.9.). A further effect of the dorsiflexion of the first metatarsal is that the relatively immobile second metatarsal is constrained to bear excessive loads. The head of the second metatarsal, which is smaller than that of the first, concentrates force over a small area and high peak pressure results. The lesser toes will also be caused to bear excessive weight bearing forces whilst the lateral metatarsals are left destabilised at both the tarsometatarsal and metatarsophalangeal articulations.

It has been suggested that a major function of the intrinsic musculature is to stabilise the vault structure of the foot (Hicks 1953b, Huson 1991, Mann 1991). Adductor hallucis and abductor hallucis are primarily responsible for the transverse stabilisation of the hallux. Having proximal origins, these muscles, with flexor hallucis brevis must also have a stabilising effect on the tarsometatarsal and tarsal joints. The interossei, likewise, have proximal origins in the tarsometatarsal ligamentous mesh which also suggests a stabilising effect on the tarsometatarsal region. With aphasic Subtalar pronation there is an alteration of muscle action. Due to the destabilisation of the joints the metatarsals are forced into adduction which causes a bowstringing of the flexor musculature (in severe cases abductor hallucis may become a flexor or even an adductor of the hallux [Root *et al.* 1977]). In contrast to muscular action maintaining the integrity of the arch, the altered mechanics exacerbate its collapse.

Orthotic therapy should aim to correct subtalar pronation or counter its effects, where possible. This must be particularly crucial where intrinsic paralysis as a consequence of neuropathy in leprosy has already compromised the integrity of foot structure. The

results of this study may indicate that this objective was achieved with tarsal cradles. These devices were prescribed where it was observed that subjects did demonstrate hyperpronation of the subtalar joint. The suggestion that the tarsal cradles do address the challenge imposed by hyperpronation and that hyperpronation is associated with ulceration require further study. Reliable objective measurements of joint kinematics are currently being developed. It must be hoped that the hypotheses suggested above may be tested in due course.

2.4.2.2 Plantar metatarsal pads

Where there was no evidence of hyperpronation, subjects were supplied with plantar metatarsal pads (PMP) incorporating appropriate cut away sections. 13 of these devices were supplied and 10 were associated with ulcer resolution. The primary function of the PMP is palliative. To be consistent with a view suggested earlier, orthotic treatment should, where possible, aim to address the underlying functional deviations implicated in the trauma. With many of the subjects in this trial the orthotic correction of claw toe deformity was not an option. The disorganisation of digits was a common finding. Partial amputation, malalignment and / or loss of muscle tendons due to past trauma and infection dictated that individual hyperextended digits were beyond orthotic correction.

Plantar metatarsal pads were prescribed mainly where digital deformities unrelated to rearfoot malfunction had caused a plantarflexion of metatarsal heads. Where chronic fixation, dislocation or subluxation of the metatarsophalangeal joints was presented, the PMP was applied to palliate the metatarsal heads by redistributing the load. The devices were designed to address the alignment of the metatarsal heads. The relatively elevated metatarsal heads are brought into ground contact whilst cut away sections accommodated ulcerated metatarsal heads. Where feet presented with mobile claw toes or retracted toes which forcibly plantarflexed the metatarsals, the PMP was in some cases augmented by the supply of digital splints. It was considered that by supplementing the PMP with these devices, functional factors implicated in the plantarflexion of the affected metatarsal were addressed. This conjecture is based on

consideration of metatarsophalangeal mechanics.

The primary function of the toes is the stabilisation of the metatarsals as the heel lifts and weight is transferred to the forefoot (Huson 1991). To facilitate this function these highly mobile units must themselves be stabilised against the ground. As the toes respond to ground reaction by extending at the metatarsophalangeal joint and at each interphalangeal joint, they are stabilised by the digital plantarflexors and the plantar aponeurosis. However, digital stabilisation is not possible until interphalangeal joint congruity is established and secured. These highly mobile kinematic chains are converted into rigid beams by the complex extensor mechanism as explained by Root *et al.* (1977).¹¹

The actions of the hallux are related intimately to the function of the first ray (see Section 2.1.9.), the sesamoids, the actions of the hallucal flexors, abductor and adductor hallucis (Huson 1991). Assuming normal anatomical variables, as the first ray plantarflexes and the metatarsal head moves posteriorly over the sesamoids, the sesamoids assume more distal positions in the longitudinal grooves with which they articulate. Root *et al.* (1977) suggest that each sesamoid will determine the angle of approach, and therefore the mechanical advantage, of the investing tendons of flexor hallucis brevis. This alignment of the tendons would then assist the muscle to exert a force vector great enough to meet the demand for stabilisation when the hallux is dorsiflexed.

Clearly, digital stability and efficient function of the metatarsophalangeal joints are dependent on the interaction of the intrinsic musculature with passive structures and the extrinsic musculature. Intrinsic motor paralysis will therefore significantly affect metatarsophalangeal joint function (Huson 1991). It is commonly assumed, in the management of leprosy impairment, that claw toe deformity is an indication of motor paralysis. Whilst this may be true of a majority of cases, as a general assumption it is

11. The extensor expansion has been described as an extension of fibres from extensor digitorum longus which form a hood like structure over the dorsum of the metatarsophalangeal joint. Fibres from the hood insert into the plantar ligaments of the metatarsophalangeal joint. The hood then passes obliquely over the dorsal aspect of the proximal phalanx where its structure is enhanced by fibres from a conjoint tendon of the digital flexors (Sarafian and Topouzian 1969).

incorrect. Root *et al.* (1977) suggest diverse mechanical explanations for claw and hammer toe deformity that are not related to intrinsic paralysis.

Digital splints were used to address the excessive extension and flexion of digital deformities. The correction of buckling required the reciprocal action of dorsoplantar corrective pressure (lorimer and Neale 1986). Where orthodigital splints were prescribed they were designed to cover the three middle toes. The dorsal element covered the proximal phalanges to restrict excessive extension. A plantar element extended beneath the intermediate and distal phalanges to inhibit flexion. In one case, where this device was used for the protection of a toe apex, it was found that there had been a correction of mobile claw toe deformity that had been presented by that subject. In 3 other cases it was used to augment the treatment of metatarsal head ulcerations that were being addressed primarily with the supply of PMPs.

The success of orthodigital splints is open to conjecture. The theory expounded above has face validity but too few subjects were supplied with the devices to allow for meaningful analysis. It may have been that the same results would have been recorded had the vulnerable areas been palliated by the use of the PMP alone.

2.4.2.3 Removable PMPs

Six subjects were supplied with PMPs that incorporated elasticated straps. This allowed the PMP to be worn on the foot rather than fixed in the footwear. The author suggests that advantages of these devices include that they are less likely to be displaced when footwear becomes incompetent and that they can be worn indoors. This is an important consideration in India where it is expected that footwear will be removed before entering a home. The author does not recommend their use where there are signs of incompetent vascular return or arterial supply. Hand dysfunction and subnormal intellect may also exclude some from consideration for these devices. Subject reaction to these devices was mixed, whilst some endorsed them enthusiastically others considered them to be troublesome.

2.4.3 MICRO-MECHANICS

When Dr Paul Brand stated that the problem of ulceration was principally that of mechanics he precipitated a plethora of research that has demonstrated the association between various kinetic variables and sub pedal trauma. To a far less extent, researchers have considered kinematic parameters when seeking to explain plantar ulceration. There is, however, a further mechanical feature of ulceration that has stimulated even less research: i.e. mechanical effects at a cellular level.

Scar tissue

During the maturation or remodelling phase of tissue repair there is a decline in concentration of fibroblasts. A complex reorientation activity organises random collagen fibres into a system of optimally oriented fibres. The eventual result is the consolidation of scar tissue, which displays a maximum strength of 20% less than that exhibited by intact skin (Johnson 1989, Price 1990).

The rapid process of synthesis and lysis of collagen in the early stages of healing is reversed during maturation to the extent that the rate of lysis exceeds that of synthesis. The nature of biochemical bonding is also altered. This results in the establishment of stronger molecular structures and links between collagen fibrils and ground substance. It is fundamental therefore to promote rapid healing to discourage the excessive linkage of collagen and ground substance. The weaker bonding of collagen in developing scar allows for limited stretch as a response to stress. With maturation scar tissue does become less resilient. However, recurrent trauma during the maturation phase leads to increasing deposits of more dense and toughened mature scar organised into progressively less resilient tissue. Brand (1991) has discussed the problem of scarring as a response to recurrent trauma. He has related the common recurrence of ulceration to the cumulative degeneration of skin into scar tissue.

The application of plastercasts has demonstrated efficacy as a method to effect the rapid healing of neuropathic ulceration (Pring and Casiebanca 1982, Kaplan and Gelber 1988). Ulcers may heal within a period of three weeks. However the

recurrence of ulceration following this procedure is common, particularly where predisposing mechanical factors have not been addressed subsequent to treatment. A more subtle problem may be the effect of immobilisation on the healing response.

The realignment of collagen fibres is thought to be a response to pressure. When pressure is applied collagen releases "piezoelectric substances" (Price 1990). It is postulated that these stress generated voltages are responsible for the realignment and general maintenance of collagen.

This provides an important perspective to wound healing as it suggests that the strength of healed skin is determined by biomechanical stresses acting on healing time. The fragility of healing resulting from immobility may be reduced by permitting careful movement of healing tissue. It is not suggested that orthotic intervention of the type under review is particularly subtle. It may be, however, that by permitting the subject to be fully ambulant whilst controlling traumatic mechanical factors, the maturation phase of the healing process may also be enhanced.

2.4.4 FURTHER FACTORS INFLUENCING ULCER HEALING

Vitamin C and oxygen are fundamental factors influencing the hydroxylation of proline and lysine. When there is a deficit of these factors there follows an inhibition of collagen synthesis. Vitamin A deficiency has been recorded as delaying re-epithelialization (Zederfeldt *et al* 1986, Daly 1990). Protein deficiency results in an amino acid deficit causing a consequent lack of availability of material to structure granulation tissue. Zederfeldt *et al.* (1986) suggested that the effect protein deficiency may have on inhibiting host-defence against infection may be a more important factor. Deficiency of trace elements particularly zinc and copper, have been implicated as a cause of delayed healing. Westaby (1982) suggested that zinc deficiency inhibits healing as it is an essential agent in the process of re-epithelialization and collagen synthesis. Copper is an essential component of a collagen linking enzyme.

Other factors recorded as inhibiting wound healing include systemic and topical steroids, antineoplastic drugs, haemostatic agents, nonsteroidal anti inflammatory

drugs, nicotine and many systemic antibiotics (Westaby 1982, Daly 1990). Subjects compromised by chronic illness (notably acquired immune deficiency syndrome) including anaemia or endocrine, vascular or connective tissue disorders are predisposed to delayed healing, as are the aged. Local conditions may be compromised by the effects of antimicrobial toxicity, whilst dressings may adversely affect healing by creating an unsuitable environment for wound healing. These factors were not considered in this study.

2.4.5 SUMMARY

There was a clear indication that the orthoses were associated with significant numbers of resolved ulcers. The study continued by investigating reasons why some Experimental group subjects presented with healed ulcers whilst others did not. Some evidence was presented to suggest that, for some subjects, the initial area of ulceration may have been too great to allow for healing before the orthoses became incompetent. Successful outcomes were also confounded by non-compliance and other idiosyncratic variables. It was also conjectured that there may have been seasonal variables that confounded the results. Analysis of the effects of deformities, the site of ulceration and footwear suggested that these variables were extraneous.

CHAPTER 3

Kinetic Studies

RATIONALE:

In the previous chapter it was suggested that an effect of orthotic intervention may be the reduction of peak pressure and/or an integral of pressure and the duration of its application (PTI). To pursue this suggestion a protocol was designed to test hypotheses that podiatric orthoses do reduce peak pressure and PTI values at designated sites.

3.1 INTRODUCTION

This chapter addresses the suggestion that orthoses affect factors widely assumed to be responsible for plantar ulceration. It opens with a review of the literature wherein it is widely agreed that foci of high pressure and similar related variables (eg. shearing stress) do affect ulceration (Stokes *et al.* 1974, Ctercteko *et al.* 1981, Boulton *et al.* 1983, 1984, 1987, Duckworth *et al.* 1985).

Although it was possible to find a consensus on which parameters of force are applicable to foot pathology there is confusion over many pertinent issues. It was found, in the literature, that there were many conflicting values for "normalcy". There are also apparent divisions due to the inability of researchers to repeat the reported methodology of peers. Other authors have reported this difficulty and criticism has been levelled at researchers and systems alike for what appears to be a lamentable lack of unanimity on many fundamental criteria (Lord 1981, Hughes *et al.* 1993).

3.1.1.1 The Harris and Beath mat

The classic Harris mat (Harris footprinting Mat, Downs Surgical Ltd., Church Road, Mitchum, Surrey), designed and used by Harris and Beath (1947), remains probably the most effective method by which foot/ground pressure patterns can be recorded in field conditions. This inexpensive non-invasive method has been widely used and may be a valuable resource, particularly where more sophisticated technology would be inappropriate. The method provides a differential pressure footprinting technique illustrating the distribution of peak vertical ground reaction forces. The study conducted by Welton (1992), for example, demonstrated a valid application of the technique. She used the Harris mat in the interpretation of foot print patterns. An indication of peak pressure which can only be identified using pressure maps displaying good spatial resolution was not required and consideration of load bearing patterns, rather than peak pressure measurements were sufficient. The validity of the method is supported by studies such as that of Hughes *et al.* (1987). They established that the Harris and Beath design correlated well with pedobarographic techniques as a method for recording foot/ground pressure patterns. In recognising the merits of the Harris mat the limitations of the method are also apparent. The value of the system is limited as the sequential development of pressure patterns are not demonstrated and the static pattern that is presented does not permit quantitative analysis.

Similar direct printing methods are available. Shutrak (Shutrak, Moore business Forms Inc., 1205 Milwaukee Ave., Glenview Illinois U.S.A.) has been used successfully by Minns (1982). The Prescale method (Prescale, Fuji Photo Film Co Ltd., Paper products 2-26-30, Nishi-Azabu, Minato-Ku, Tokyo, Japan) was reported by Aritomi *et al.* (1983). Prescale is not recommended due to high pressure sensitive range of the material used (10 to 100kg/cm²).

3.1.1.2 The Barograph

Elftman (1934) developed the barograph to demonstrate the transference of pressure along the plantar aspect of the foot. Elftman's barograph was the earliest amongst

direct visualisation techniques. A plate of glass, lit from beneath was overlaid with a black rubber mat. As pressure was applied to the mat the pyramidal projections on the undersurface deformed against the glass. To emphasise the effect of the flattened rubber (which gave a dot like appearance) a white fluid was introduced between the mat and the glass. The area of each dot is an expression of local pressure, thus areas of high pressure were displayed as darker regions. Slow motion film of stance phase presented an observation of changes in pressure distribution.

Pedobarographic technique, conceptualised by Chodera (1960), has been extensively used and modified. The Pedobaroscope (John Drew Ltd., 433 Uxbridge Road, London, UK) comprises a glass plate illuminated along two opposing edges. A sheet of deformable material is positioned between the foot and plate. Where the material is depressed by the force of the foot it is pressed into contact with the glass. The internal reflection of light is disturbed and the under surface of the mat is illuminated, the flattening of the undersurface being proportional to pressure applied. A grey scale pedobarogram is the intensity modulated footprint that is produced. The immediate advantage of pedobarographic systems over direct printing is the presentation of direct observation of the instantaneous pressure distribution. The system has been developed so that the grey scale image may be enhanced by an eight zone colour display of foot pressure contours. The contours relate to the extent and position of excessive pressure and can be acquired by interposing video processing between camera and monitor. Further developments to present quantitative analysis of static and dynamic distribution, using microprocessors, has significantly enhanced the usefulness of the pedobarograph (Duckworth *et al.* 1985).

Limitations reported include those by Robertson and Delbridge (1985) who sought to define the range of "normal" forefoot pressures and pressure patterns in asymptomatic feet, using the pedobarograph. They found classification difficult due to the wide variation in pressure patterns. Other investigators using the pedobarograph, have sought to standardise walking in their subjects in order to acquire reproducible results (Holmes and Timmerman 1990).

The plastic pedograph, developed by Barnet (1954) has been considered the forerunner of contemporary floor mounted transducer matrices (Alexander *et al.* 1990). The apparatus was constructed with 640 vertically mounted clear plastic rods resting at their lower end on a sheet of rubber. Each row of rods was marked on the vertical lateral face 0.37 inches below the level of the adjacent row. Each rod was caused to sink into the rubber at an amount proportional to the pressure applied, deflecting the horizontal marker downward correspondingly. Illuminated from the side the device presented a two dimensional graph of foot pressure. Although Barnet suggested that the rods could be calibrated and that the results were quantifiable (a suggestion refuted by Alexander *et al.* 1990), the procedure was laborious and impracticable.

3.1.1.3 Floor mounted transducer matrices

Hutton and Drabble (1972) presented a force platform to be positioned in a walkway. The device was designed to be positioned longitudinally or horizontally in order that forces under specified areas of the foot could be measured. The force platform they designed was reliant on the measurement of longitudinal tension by four strain gauges from which 12 1.4 x 25cm beams were suspended. This device does not appear to have satisfied research criteria. The device described by Hutton and Drabble was small (25cm x 17 cm) and four passes by the subject were required to build a composite image of the foot. The positioning of the foot across the transverse beams was not shown to be repeatable with consecutive walks and as a consequence the composite graph was subsequently smoothed out. Already compromised by limited resolution suggested by broad transverse beams (1.4cm) the internal validity of their method appears questionable. Hutton collaborating with Dahendran developed a transducer matrix comprising an array of load cells consisting of 25mm diameter steel rings each with four strain gauges. The load cells (each 1.5 x 1.5cm) were positioned into a 25 x 15cm. floor mounted matrix. Their objective was to study reaction forces at eight predetermined areas of the foot. However, the size of the force platform (25 x 12.5cm) was small and targeting would have been inevitable. Four passes were made and presumably a mean value for each area was calculated. Whether four passes were adequate is questionable as variation in peak pressures at individual sites would

be further compromised by an inevitable overlap on individual load cells (Hutton and Dahendran 1981).

Hughes *et al.* (1987) compared the performance of the Harris mat, pedobarograph and dynapod. The latter features a floor mounted transducer matrix described by Dhanedran *et al.* (1978). Neither pedobarograph or the dynapod system was without criticism. Whilst the pedobarograph lacked accuracy and was found to be slower than the dynapod, the dynapod consistently misrepresented pressures beneath the toes. Alexander *et al.* (1990) express reserve in their consideration of the dynapod. They suggest that inaccuracy appears inevitable where a small load sensitive platform is coupled with a transducer surface area exceeding some of the areas of interest on the foot. These observations emphasise the caution with which researchers should evaluate results if characteristics of individual measuring devices are not carefully considered.

Developments have been made on the strength and weaknesses of earlier initiatives and currently available commercial systems demonstrate the extent to which earlier criticism has been addressed. Alexander *et al.* (1990) describe the Emed SF System (Novel Inc. Munich Germany). This system is the result of extensive modification of earlier capacitance mats. The system uses 1344 capacitance transducers in a sensitive area measuring 34 x 20 cm. The active measuring area is set flush in a 6m walkway. Time resolution varies from early equipment which scans 20 times s⁻¹ (demonstrated by Hughes *et al.* 1987) to updated versions which scan 60 s⁻¹. Data relating to the area of contact, total force and peak pressure for the entire foot and individual sites can be retrieved for analysis. Contact time, expressed in ms, is augmented by recording of the percentage of stance phase for individual sites during contact. For each site of interest, pressure and force time integrals as well as the instant of peak pressure and force are also presented as a percentage of stance phase. Non-SI units are produced.

The Emed SF System offers an opportunity for accurate objective documentation of time dependent pressure distribution and loading patterns. Mean values are displayed

immediately after a walk on a colour monitor whilst detailed information is recorded on disc for further analysis. (Further detail relating to the EMED system is presented later.)

3.1.1.4 Inshoe devices

The application of floor mounted systems is limited to study of events at the foot/ground interface and as such do not relate directly to events at the foot shoe interface. Concurrent with much of the technology that has been developed to measure foot/ground events has been the development of discrete inshoe sensors. Soames *et al.* (1985) demonstrated the successful use of a conductive transducer constructed with beryllium copper. The reliability of measurement was dependent on the accurate positioning of transducers. Potential effects of variation in the positioning of the transducers is as much a current issue as it was when Soames *et al.* (1982) committed their system to trial. Protagonists of the opinion that transducers should be positioned onto a rigid surface argue that accurate readings are dependent on the even loading of transducers. If a transducer is positioned on the foot surface it may be displaced proximally at the instant of maximal force which could be focused at an anatomical position distal to that covered by the transducer (Lord 1981). Consistent results suggest that Soames *et al.* (1982) were able to place transducers successfully, although the time consuming nature of accurate placement was commented on. Others have demonstrated repeatability in palpation techniques (Mclauchlan *et al.* 1993).

Miyazaki and Ishida (1984) used capacitance transducers to improve on an early device designed to use a strain gauge. Capacitance transducers work on the principle that when pressure is applied to an insulation matrix separating two conducting layers, the capacitance of the device alters. With an alteration in capacitance, voltage output is affected as is the consequent recorded voltage output. Calibration allows voltage output to be related linearly to force.

A problem with capacitance transducers is that the delicacy of the transducer is such

that the prolonged or repeated deformation of the load sensitive part of the device will alter the response. Transducers should therefore be calibrated before each use.

To demonstrate the effects of various forms of footwear and insoles on sub-pedal pressure, Bransby-Zachary *et al.* (1990) used an Entran transducer. This device contains a silicone strain gauge with a metal diaphragm. (The basic principle of the strain gauge is that there is an alteration in resistance as a response to force.)

Criticism of earlier devices using strain gauges included marked awareness of the device and variable transducer sensitivity (Miyazaki and Iwakura 1978). The device described by Bransby-Zachary *et al.* (1990) appears to have addressed these characteristics and features that were identified as problematic with other strain gauge systems.

McLauchlan *et al.* (1993) embedded transducers into an insole constructed from rubberised cork and regenerated leather when they tested the reliability of the Gaitscan system. This system uses 8 piezoelectric copolymer transducers measuring $10 \times 10 \text{ mm}^2$. Each transducer is 2.8 mm thick. Anatomical sites of interest were defined by the researcher who located the sites specified by palpation. Marks made at each site were transferred to the insole to indicate the positions for embedding the transducers. Transducers were connected to an ankle charge detection box wherein the charge signals, from the transducers, were converted into a voltage output. Voltage was then transmitted to a console and thence to a P.C. for data acquisition and storage for later analysis. The system demonstrated reliability with correlation values ranging from 0.70 to 0.99.

Alexander *et al.* (1990) discussed the methods of other researchers who implanted transducers into rubber insoles. Problems identified included breakage of fine wires from the transducers, hysteresis and creep of rubber. Furthermore, load cells were found to deform with bending in the shoe causing difficulties with data interpretation. The device Bransby-Zachary *et al.* (1990) used was discrete temperature stable and demonstrated 0.5% full scale error for combined hysteresis and nonlinearity.

Although demonstrating enlightened ingenuity, the development of inshoe measuring devices discussed thus far have been able to describe only the vertical component of pressure. It has been postulated that the shear component of pressure may be the determinant of tissue trauma. (Pollard *et al.* 1983, Lord *et al.* 1986, Brand 1988). By using a transducer based on a magneto resistive principle, Lord *et al.* were able to demonstrate high posterior shear stress during the propulsive phase of gait (Lord 1992).

The shear transducer developed by Pollard *et al.* (1983) works on the principle that when a semi conductor field coil is translated in a magnetic field, the relative displacement of the two components causes a change in coil resistance. A measurable change in coil resistance is produced that is proportional to the force applied to effect displacement.

The components of Pollard's transducer comprise 2 stainless steel discs, one with a groove and another with a corresponding ridge. A semi conductor field coil and a magnet are situated in the groove and ridge respectively. The discs are separated by a layer of silicone rubber which limits excursion. The composition of the components is such that translation of the coil is restricted to one plane. However as the orientation of the transducers may be varied, measurement of shear in multiple directions may be acquired.

Technology has facilitated radical changes since the early innovations of Beely (cited in Elftman 1934) who attempted to quantify foci of sub pedal high pressure by examining the negative plaster cast impressions of weight bearing feet. When Bauman *et al.* used capacitance transducers in 1963 they expressed a hope that it might eventually be possible to quantify shearing stress. Now that their hope has been realised (Pollard 1983, Lord 1992) it may be anticipated that an increased access to technology will continue to stimulate further advances. However, there is concern expressed by a number of researchers who welcome technological development with reservations. Some have already identified confusion relating to methods of investigation and interpretation of results which they attribute, in part, to the wide

array of available equipment. (Hughes *et al.* 1987, Lord 1981). Greater efforts should be made toward the standardisation of methods and analysis if understanding is to keep in pace with technology.

3.1.2 TISSUE STRESS: THE RELEVANT PARAMETERS FOR MEASUREMENT

In searching the literature for relevant clinical information there was an increasing frustration with the difficulty of identifying comparable items of research. Lord (1986) and Hughes (1991a) both experienced similar dissatisfaction. They identified the problem as being the result of the variety of systems, weak methodology, lack of a cohesive analytical approach and frank confusion in the identification of relevant parameters. However, within these limitations significant advances have been made in the use of pressure measurement systems to present reliable clinical findings.

3.1.2.1 Peak pressure

Peak pressure measurements are generally taken to represent short transient episodes during which vertical force, under a fixed area, is divided by that area. Local pressure values, therefore, are dictated as much by the area of the transducer used as it is by the applied force. Consequently, measurement will demonstrate a value between actual peak pressure and the value of total load applied over the transducer. This effect will confound attempts to compare studies, where different measurement systems have been used, unless values can be extrapolated and juxtaposed.

The construct validity of peak pressure measurement is demonstrated by numerous findings where an association between peak pressure and trauma has been reported. However, the question whether peak pressure per se is implicated in tissue stress remains to be resolved. Some have voiced reservations relating to this issue (Duckworth *et al.* 1985, Lord 1986). Where peak pressure has been cited as demonstrating an association with tissue trauma it is possible that it is because it reflects an increase in shearing stress. Shearing stress, which is an expression of

tangential force, cannot increase without a corresponding increase in perpendicular force (parallel force in the absence of sufficient perpendicular force will only be demonstrated as sliding friction) (Cavanagh *et al.* 1991a). However the degree to which vertical force contributes to shear remains difficult to assess. The relationship is intriguing and may be critical. Bennet *et al.* (1979) demonstrated that direct pressure required to occlude blood flow was halved in the presence of shear.

An expression of pressure and duration of pressure applied may prove a more valid correlate of tissue trauma than peak pressure. Such a parameter indicates an implicit involvement of shearing stress. This suggestion is pursued in greater detail later. The basis of this hypothesis is best explained by consideration of the course of the centre of force as it traverses the foot during the stance phase of gait. This hypothesis is supported by Hughes *et al.* (1991) who suggested that joint consideration of peak pressure values and the duration of peak pressure are probably the best indicators of the malfunctioning foot.

3.1.2.2 Transmission of forces during gait

In 1934 Elftman and Manter (1934) developed the concept of a force curve. Their objective was to demonstrate how the distribution and approximate time intervals of force could be determined by measurement of the progression of the centre of gravity through the foot. It demonstrates how forces, originating from the trochlear surface of the talus, radiate in straight lines toward the ground through the foot at every point where the foot makes stable contact (Schwartz and Heath 1964, Root *et al.* 1977). Taking the mean direction of each line at contact, a distribution of points, on a footprint, can be plotted which represent the relation of time and direction of forces acting on the foot.

Kato *et al.* (1983) describe a method by which an image of the foot can be subdivided to facilitate the classification of the location of centre of pressure patterns. Tangential lines to the most prominent points on the medial and lateral sides of the foot can be drawn and the angle between these two lines can be bisected. The

bisection line describes the midline of the foot and is used to define the medial and lateral aspects of the foot. Dividing the line transversely into three equal parts, the sections may be designated as forefoot, midfoot and hindfoot. A simple procedure, this approach provides reference points that reduce the subjective bias inherent in interpreting curve peculiarities discussed below.

Where normalcy refers to the 3 typical components of the force curve (the pronatory curve, the supinatory curve and the straight propulsive line), deviations from normalcy (i.e. a reduction in the radii of either the pronatory or supinatory curves) may indicate a pathological response (Root *et al.* 1977). The illustration of trajectory deviations is considered to be indicative of structural or functional abnormalities and as such it is a valuable diagnostic aid. Synchronised with a trajectory demonstrating the magnitude of ground reaction forces, or the progression of localised pressure, an opportunity for detailed analysis is presented. Information relating to pressure, location of loading and duration of loading furthers diagnostic ability by suggesting the potential effect of abnormal tread. The combined advantage of cause and effect are illustrated in this composite approach.

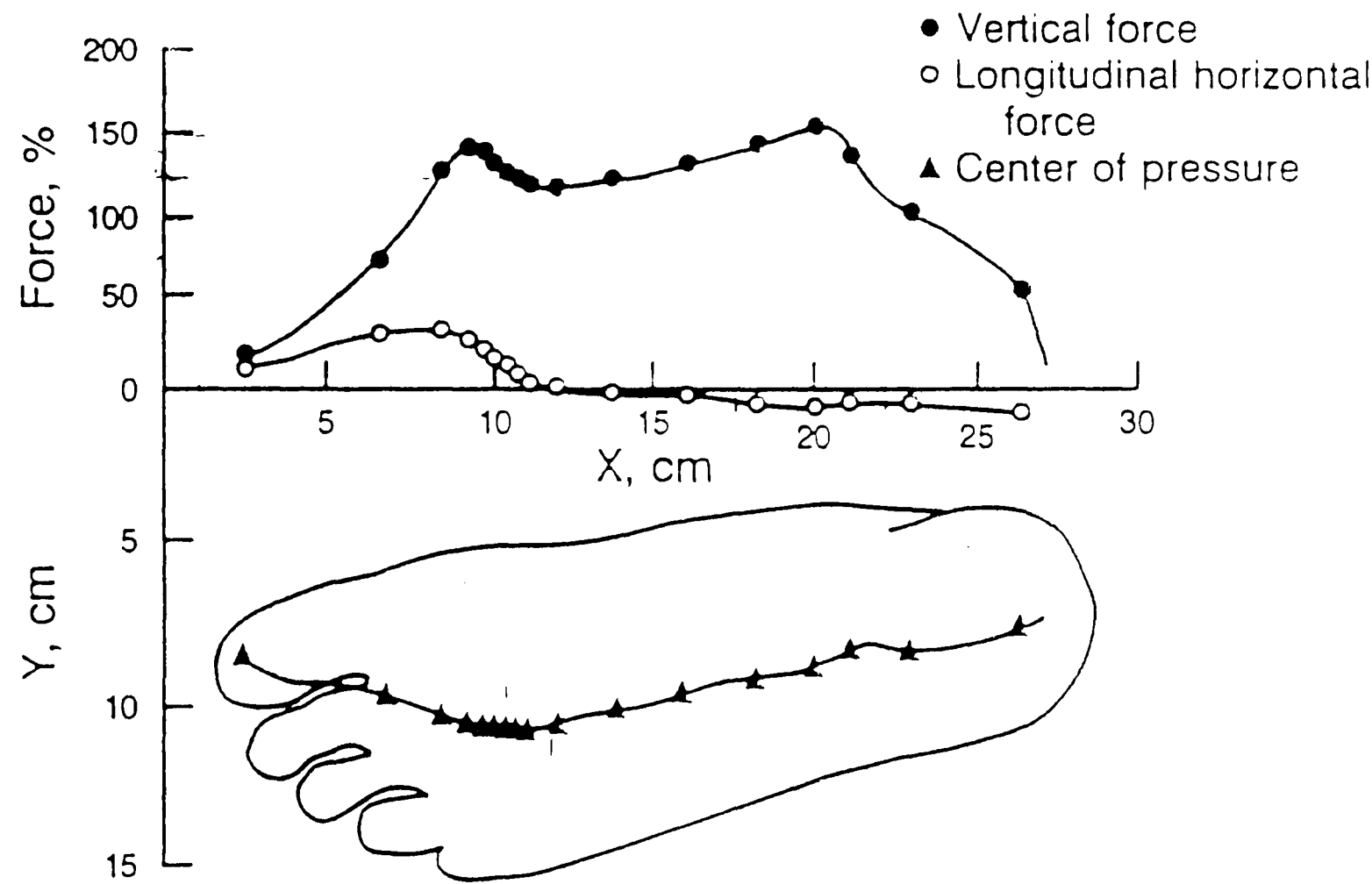
3.1.2.3 The force trajectory

It was Grundy *et al.* (1975) who first correlated the force trace with stance phases by simultaneous study of the trajectory of the centre of foot pressure and a video of plantar contact. By so doing they were able to illustrate the relationship between the centre of foot pressure and the foot print, with force against distance.

It is generally accepted that a vertical reaction force is equal to the integral of pressure over the area of contact. It follows that the centre of pressure is the central point of the initial moment of pressure over the same area (Lord 1981). The course of force is well recognised as describing a double hump when illustrated graphically (Soames 1985, Bransby-Zachary *et al.* 1990). Following initial postero lateral heel contact, during normal walking, there is a rapid progression of the centre of pressure to the forefoot. As the foot progresses through 25% of stance phase, ground reaction force reaches its first peak which approximates 15% above body weight. At this

Figure 21

From:
Alexander *et al.* (1990)



period, the heel, lateral aspect of the midfoot and the metatarsals have established ground contact. There is a reduction to approximately 80% body weight at midstance attributed to body weight being supported by both rearfoot and forefoot. The heel and midfoot maintain ground contact for approximately 50% of stance phase. There is a marked deceleration of the progression of the centre of pressure as early as 40% of the stance phase. The force ascends to a second peak of similar magnitude to the first, at approximately 80% of the stance phase, during which time the heel has lifted and the metatarsals are bearing all the weight. Considering the product of applied force and contact time it is apparent that the forefoot is required to bear loads almost three times greater than the heel. This observation is discussed in further detail later (Pollard *et al.* 1983, Soames *et al* 1982, Soames 1985) .

3.1.2.4 Foot floor impulse

Kato *et al.* (1983) described the term "foot floor impulse" to represent the product of ground reaction force and the time of force application. In their study, time was recorded for the percentage of stance phase that the centre of pressure was located at, on any given region of the foot. The significance of this development was that three components of ground reaction force could be observed. As stated, the body decelerates at foot contact, and accelerates with the elevation of the centre of mass to mid stance. Deceleration and acceleration of progression are features of forefoot loading and the subsequent displacement of the centre of mass at propulsion. Vertical ground reaction forces correspond simultaneously with horizontal reaction forces. A fore and aft shear pattern (antero-posterior horizontal shear) is the resultant of initial horizontal and vertical forces with deceleration at contact, and the displacement of the body over the stance foot. Further medio-lateral horizontal shear illustrates the influence of transverse rotations of the weightbearing limb. An initial medial shear is possibly the result of the adducted posture of the foot at contact. With progressive abduction of the hip from mid stance, a lateral shear force is created (Mann 1991). The impulse distribution parameters Kato *et al.* (1983) described are vertical impulse, fore-aft impulse, and medio-lateral impulse. By way of example, vertical impulse is identified as the product of vertical ground reaction force and the period of interest. The implications are that if the progression of the centre of pressure is faster

over a defined area than it is over another, the impulse will be less, for equivalent pressure, at the area over which the centre of pressure passed quickest. A similar expression is described as the pressure time integral (PTI) by Soames (1985) who indicated that it represents a change in momentum demonstrating both acceleration and deceleration of the subject.

The improved resolution available with transducers demonstrating a high frequency response rate (50Hz. or more) allows detailed analysis of the pressure profile (Bransby-Zachary *et al.* 1990). The asymmetry of the forefoot peak had been described by Soames (1985), but the significance of the finding was not discussed until it was analysed by Bransby-Zachary *et al.* (1990). They suggest that where graphs of peak heights and peak duration show only minor variation a useful comparison of "secondary peaks" may be made. This conclusion was drawn from a study that demonstrated that an increase in PTI could not be attributed to prolonged forefoot contact time. Their observation led them to postulate that the increased PTI was due to higher impact pressure. This suggestion was supported by measurement of the "impact peak". They described the double peak profile as demonstrating peak pressure as the roll off load with the secondary peak as the impact load. Where peak pressure and peak time remained constant any changes under the curve (PTI) represent changes in the total impact load.

Bransby-Zachary *et al.* (1990) found that whilst alterations in footwear and the use of insoles had little effect on peak pressure which normally represents roll off, they had a significant effect on impact pressure. If the "impact peak" demonstrates the effect of deceleration it represents a high quotient of horizontal force that would be the expression of shearing stress.

3.1.2.5 Barefoot walking

The reason that dynamic foot pressure measurement must take preference over static measurement is that the foot's major function is locomotion. Evidence cited earlier clearly relates ulceration to dynamically induced trauma and for this reason static measurement is not considered here. The general principles relating to the

progression of the centre of force have been presented earlier and are not repeated here. However, by way of introduction to what follows, the familiar double peak of vertical pressure is considered, as, in isolation, it demonstrates an inadequacy. As has been reported earlier, the two peaks are similar in magnitude (approximately 10 to 20% above body weight). However the load dwells in the area of the metatarsal heads (hereafter referred to as MTH) considerably longer than it does in the heel. The implication is that although forces at the heel and forefoot are of similar magnitude, the load bearing function of the forefoot is three times that of the heel (Grundy *et al.* 1975, Lord 1986, Alexander *et al.* 1990). Studies consistently demonstrate that peak pressures at the heel are not reached until the foot has moved through 25% of the stance phase, by which time the forefoot is already in contact with the ground.

Reports of overlap in extent of duration between the rearfoot and MTH area vary. Scranton and McMaster (1976) reported that the rearfoot was in ground contact for 45% of stance phase whilst the forefoot claimed contact for 63% of stance. Soames (1985) however recorded heel and midfoot contact lasting 60% of stance with the MTH area in contact for as much as 80% of stance. A significant observation made by Soames was that peak pressures at the MTH area were not reached until the foot had progressed through 80% of the stance phase. The implication is that forefoot locations alone experience peak pressures in isolation and that the period of forefoot loading is significantly greater than either the rearfoot or midfoot.

Studies of the progression of the centre of force across the forefoot yields variable patterns of weight bearing (Hughes *et al.* 1993). Most investigators agree that pressure peaks under the second or third MTH (Betts *et al.* 1980a, 1980b, Soames 1985, Roy 1988, Rodgers and Cavanagh 1989). In feet where the highest peak pressure may be under the second MTH the highest load may still be under the first MTH. This is explained by the observation that the second MTH has an area approximately half that of the first MTH. A pattern of central loading (second and third MTHs) has been demonstrated as the most commonly occurring of four patterns of pressure distribution. The other common patterns have been defined by Hughes *et al.* (1993) as: medial/central (first and second MTHs), lateral (high central and lateral pressure with relatively low medial pressure) and medial (highest pressure medially).

They established that of these groups, those defined as lateral were the second most commonly occurring group. The frequency of medial and medial/central groups was found to decline respectively.

Whilst contributing useful criteria for normalcy the findings related above may be limited in their application to Caucasian populations. Further study of other populations, using the same system, should be undertaken to establish validity. A further limitation of Hughes study is that it cannot be generalised to shod populations. This point is emphasised by consideration of a study conducted by Soames *et al.* (1982). In comparing barefoot and shod subjects, they indicated that there is a considerable deviation from established barefoot patterns in findings relating to shod subjects. Shoes appear to exert a generally beneficial effect on pressure distribution at the heel. It was found that barefeet demonstrated a centre of pressure line through the central metatarsal heads with the highest peak pressures at the 3rd. metatarsal head. In shod subjects, however, a medial shift of maximum pressure to the 1st. and 2nd. metatarsal heads was recorded. The peak pressure measurement and contact time of the toes was found to be consistently increased in shod subjects. This was attributed to alterations in weight transfer with a reduction in the demand for weight bearing on the metatarsal heads.

3.1.3 PROCEDURES FOR DATA COLLECTION

Hughes *et al.* (1991a) used the EMED system to establish coefficients of reliability for force related parameters measured at varying speeds. Their contribution has been particularly useful in that they have demonstrated the reliability of measurement relative to the number of recorded events. They studied data relating to single step, mid gait events and established individual coefficients of reliability for all the force parameters that can be measured using the EMED system. They found a 0.904 reliability coefficient for a mean of three walks, and suggested that at least three measurements should be made for reliable comparisons. They also recommended that, since there is intersubject walk to walk variability, studies will be more reliable where one individual is compared to himself.

Lord and Hosien (1994) used the F Scan gait analysis system (version 1.2.) to assess the effects of moulded insoles as a method of peak pressure reduction. They reported limitations that restricted the recording of data to a 4 second period in the mid walk of three walks. This method was repeated so that two periods of data collection for each subject was made possible. This protocol generated two sets of data for each subject, which represented events relating to six steps. Citing the recommendation of Hughes *et al.* (1991) they suggested that three periods of data would have provided more reliable findings. However the findings of Hughes *et al.* were based on single mid gait events and therefore relate to three steps from consecutive walks.

3.2 METHOD

3.2.1 THE MIKRO EMED INSOLE

The Mikro-Emed¹¹ system is described as a fully portable, dynamic pressure distribution acquisition system. It was designed for the use with various sensor matrices based on capacitive principles. The insole used for this investigation (EMED size 10) incorporated a flexible sensor arrangement with sensors decoupled from each other in a flexible foil matrix. The insole could, therefore, adapt to surfaces which curved in more than one direction. Being flexible and light weight (< 1000g) it did not interfere with subject performance. The temperature dependency of the system is minor (< 0.04 N/cm²/°C). It has a maximal sampling frequency of 100Hz. with 85 sensors.

(For details of calibration please see Appendix 6)

The data format of the MICRO EMED is compatible with standard EMED software. The display and print-out software used for this investigation was EMED-DEMO which creates ASCII-files containing the pressure value for each sensor, total force, maximum pressure, contact area, and centre of pressure co-ordinates from EMED data files. Analysis Software used was EMED-MULTIMASK which presented analysis of pressure distribution measurements from manually defined areas of interest. Definition of threshold values and automatic calculation of fundamental parameters for total object and defined areas (in absolute values and as percentage body weight) was presented with the centre of pressure line.

11. Novel gmbh, Beichstr. 8, D-80802 Munchen, West Germany.

3.2.2 SIMULATION

A convex vitrethene disc 2cm in diameter, 2mm thick was constructed. The disc was to be taped to the investigators foot to simulate anatomical abnormality at designated sites. The sites chosen for consideration were the first, and then second metatarsal heads of the right foot.

3.2.3 KINEMATIC PARAMETERS

With the vitrethene disc taped to the skin beneath the first metatarsal head, cadence was registered by timing steps on a treadmill set at 4m.p.h. Cadence was thereafter standardised using a metronome set at the timing established on the treadmill.

Tests were conducted in a corridor approximately 30 metres in length. Before each test the subject, with the vitrethene disc adhered to the site of interest, traversed the corridor freely to become accustomed to successive test conditions.

Each test generated data relating to eleven, right foot stance phase events. Data collection commenced with the third right step (stance phase of the second gait cycle) and terminated with the eleventh right step of walks extending through at least fifteen gait cycles. All data were stored in the EMED analysing system for subsequent analysis.

3.2.4 DATA COLLECTION AND ANALYSIS

1st. Simulation:

2cm. convex vitrethene disc adhered to the skin under the first metatarsal head (right foot).

1st. Simulation control data

Data representing peak pressure and PTI values dependent on the effects of Vizianagram Leprosy sandals with 8mm micro-cellular rubber insoles (18⁰ shore) were collected. These data were referred to as *Baseline 1*.

1st. Simulation experimental data

Peak pressure and PTI values were subsequently collected under two experimental conditions:

1. The same sandals with the right sandal modified to include a tarsal cradle extending to a bevelled edge proximal to the webbing of the toes and incorporating a wing to the first metatarsal head.
2. The same sandals with the right sandal modified to include a cobra pad.

Data from the 2 successive experimental conditions were compared with *Baseline 1*. data using the Wilcoxon signed ranks test.

2nd simulation:

2cm. convex vitrathene disc adhered to the skin under the second metatarsal head (right foot).

2nd simulation control data

Data representing peak pressure and PTI values dependent on the effects of Vizianagram Leprosy sandals with 8mm micro-cellular rubber insoles (18⁰ shore) were collected. These data were referred to as *Baseline 2*.

2nd simulation experimental data

Peak pressure and PTI values were subsequently collected under three experimental conditions:

1. The same sandals with the right sandal modified to include a plantar metatarsal pad extending to a bevelled edge proximal to the webbing of the toes and incorporating a 'U' cut away beneath the area of the second metatarsal head.
2. The same sandals with the right sandal modified to include a tarsal cradle extending to incorporate a metatarsal bar immediately proximal to the metatarsal heads.
3. The same sandals with the right sandal modified to include a metatarsal bar.

Data from the 3 successive experimental conditions were compared with *Baseline 2*

data using the Wilcoxon signed ranks test.

In the order described above, successive devices were adhered to the right sandal using twinstick tape. This facilitated the temporary, yet firm attachment of devices. The flexible Mikro-Emed insole was placed over the weight bearing surface of the sandal, in compliance with successive test demands, and was secured in position by micropore surgical tape.

3.2.5 TEST RETEST CONDITIONS

At the culmination of the experiment, test conditions were repeated under which first control data was collected (i.e. Vizianagram sandal without modifications supporting a bare foot with a simulated anatomical abnormality at the first metatarsal head.). Test conditions were compared using the Wilcoxon signed ranks test. Using this approach, potential systematic source of error was addressed thereby satisfying demand for reliability.

3.3 RESULTS

Figures 22 and 23 demonstrate the affects of a modified tarsal cradle (type 1) and a cobra pad on peak pressure and pressure time intregral findings under the conditions of the 1st simulation. Data corresponding to these bar charts is presented in tables 18 and 19.

Figures 24 and 25 demonstrate the affects of a modified tarsal cradle (type 2), a p.m.p. and a metatarsal bar on peak pressure and pressure time intregral findings. Data corresponding to these bar charts is presented in tables 20 to 23. The test-retest results are presented in table 24.

Figure 22

First simulation: The effects of orthoses on peak pressure

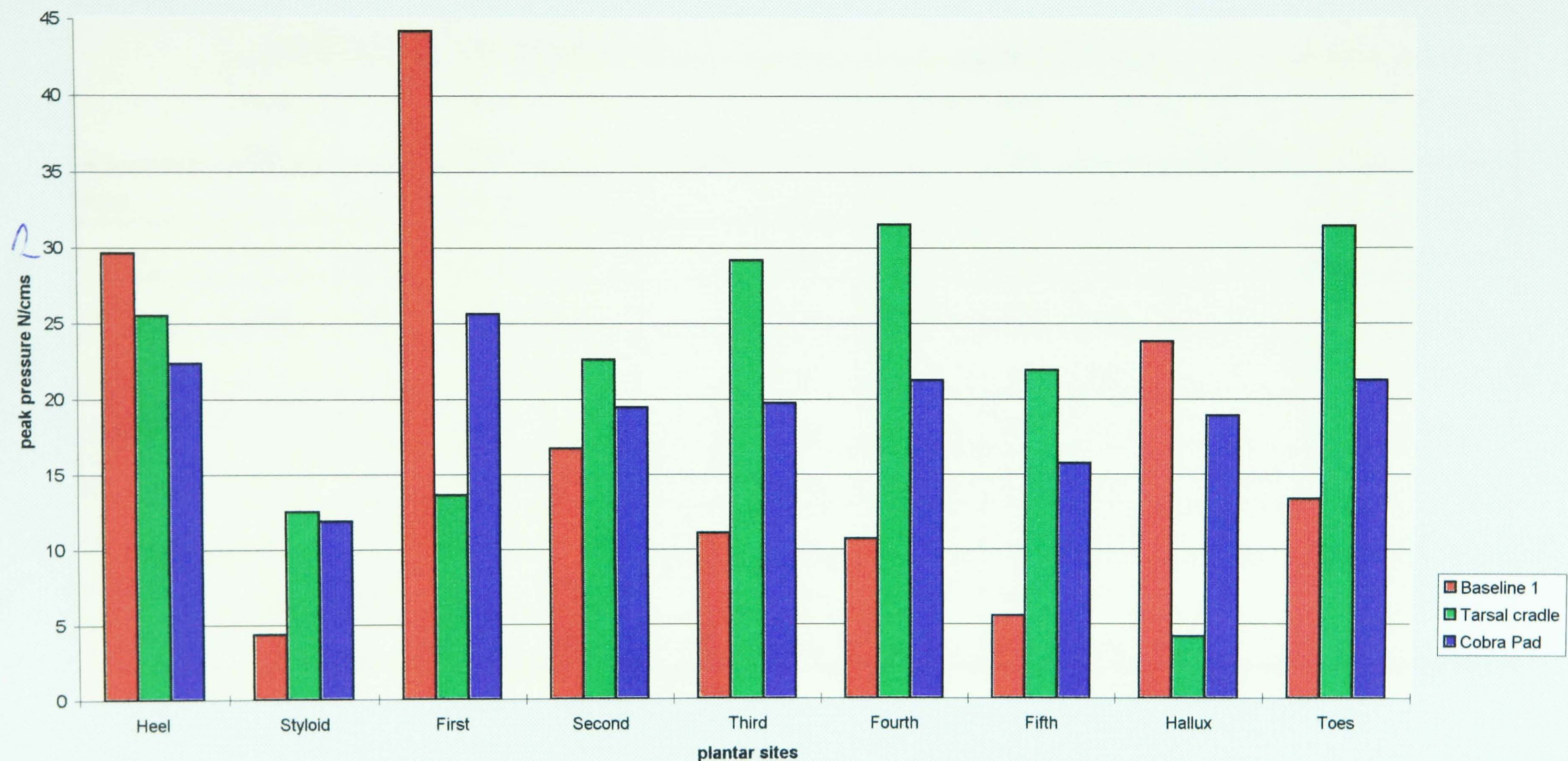


Table 18: Comparing Peak Pressure at Baseline 1 with Peak Pressure Dependency on Modified Tarsal Cradle and Cobra Pad.

	Baseline n = 11		Tarsal Cradle n = 11					Cobra Pad n = 11				
	Mean	s.d.	Mean	s.d.	< or >	P	95% C.I.	Mean	s.d.	< or >	P	95% C.I.
	Ncm ²		Ncm ²		Baseline	Value		Ncm ²		Baseline	Value	
Heel	29.64	2.12	25.55	3.58	<	0.01	.5 to 7.5	22.36	1.87	<	0.002	4.5 to 9.5
Styloid	4.36	0.5	12.55	0.99	>	0.001	-9 to -7.5	11.91	1.45	>	0.001	-8.5 to -6.5
1st. Met	44.27	3.16	13.64	2.53	<	0.001	28.5 to 35	25.64	2.29	<	0.001	15.5 to 21
2nd. Met	16.73	1.01	22.64	1.15	>	0.001	-7 to -5	19.45	1.04	>	0.002	-3.5 to -2
3rd. Met.	11.09	1.87	29.18	1.27	>	0.001	-20 to -16	19.73	1.19	>	0.001	-10 to -7
4th. Met	10.73	2.2	31.55	2.81	>	0.001	-24 to -17.5	21.27	1.79	>	0.001	-13 to -8.5
5th Met.	5.55	2.16	21.91	3.23	>	0.001	-20 to -13	15.73	2.15	>	0.001	-13 to -8
Hallux	23.82	1.08	4.13	1.27	<	0.005	17.5 to 21	18.91	1.51	<	0.006	3.5 to 6
Toes	13.36	0.5	31.45	2.97	>	0.001	16 to 21	21.27	1.71	>	0.001	-9 to -6.5

Figure 23

First simulation: The Effects of Orthoses on P.T.I.

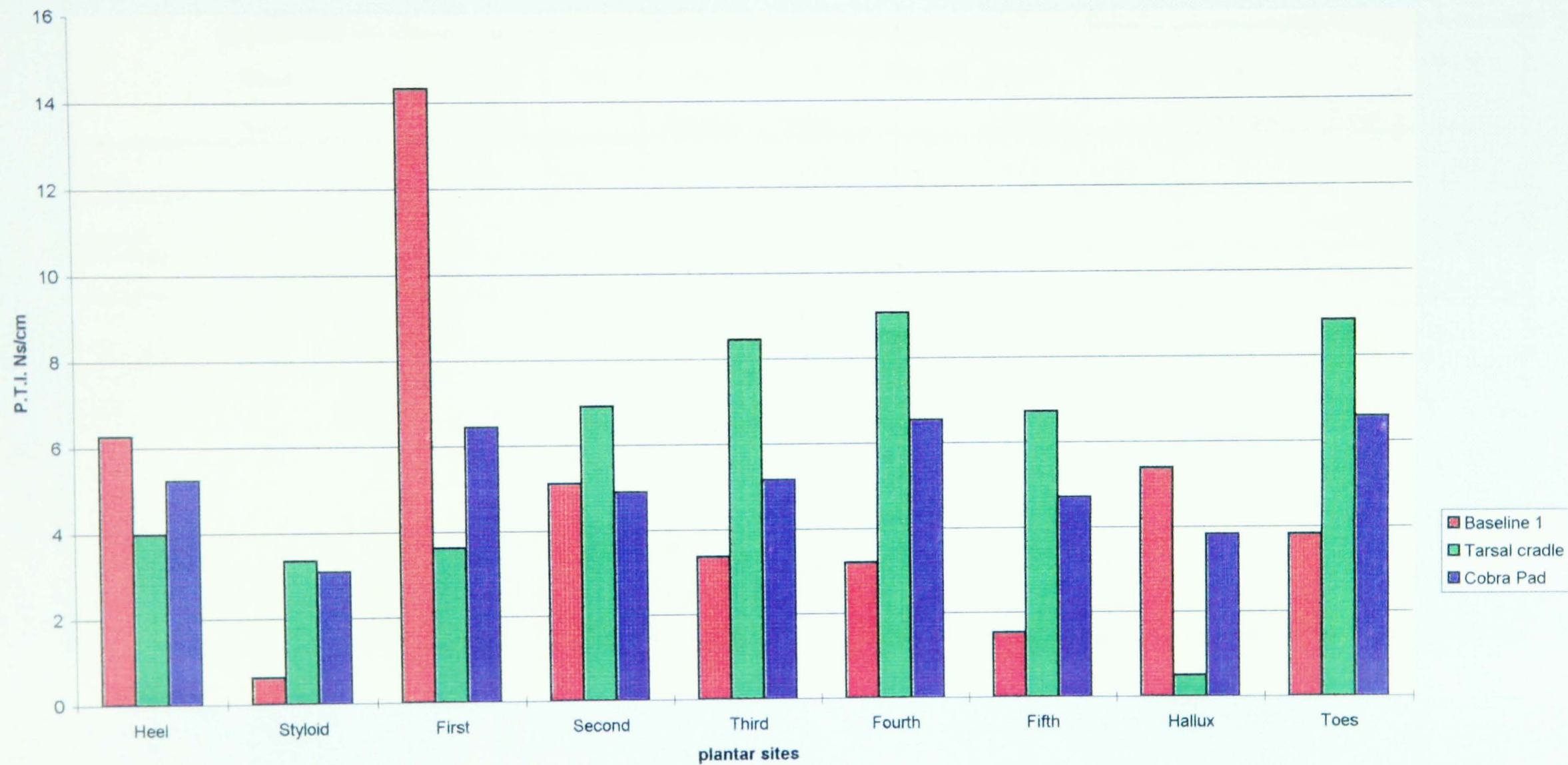


Table 19: Comparing P.T.I. at Baseline with P.T.I. Dependency on Modified Tarsal Cradle and Cobra Pad.

	Baseline n = 11		Tarsal Cradle n = 11					Cobra Pad n= 11				
	Mean Nscm ²	s.d.	Mean Nscm ²	s.d.	< or > Baseline	P Value	95% C.I.	Mean Nscm ²	s.d.	< or > Baseline	P Value	95% C.I.
Heel	6.26	0.46	3.99	0.33	<	0.001	1.8 to 2.6	5.24	0.45	<	0.01	.5 to 1.6
Styloid	0.62	0.06	3.35	0.29	>	0.001	2.5 to 3	3.09	0.32	>	0.002	-2.7 to -2.2
1st. Met	14.33	1.27	3.63	0.71	<	0.001	9.4 to 12	6.44	0.95	<	0.001	6.7 to 9.25
2nd. Met	5.11	0.2+6	6.91	0.51	>	0.001	-2.25 to-1.3	4.90	0.45	<	N.S.	-9 to .5
3rd. Met.	3.36	0.56	8.45	0.56	>	0.001	-5.5 to -4.5	5.16	0.49	>	0.001	-2.3 to -1.4
4th. Met	3.20	0.66	9.06	0.89	>	0.001	-6.7 to -5	6.54	0.86	>	0.001	-4.1 to -2.5
5th Met.	1.53	0.67	6.73	1.15	>	0.001	-6.3 to--4.0	4.71	1.20	>	0.001	-4.1 to -2.2
Hallux	5.39	0.45	0.50	0.30	<	0.003	4.1 to 5.6	3.83	0.54	<	0.005	.94 to 2.9
Toes	3.82	0.37	8.84	0.88	>	0.001	16 to 20	6.58	0.84	>	0.001	-3.4 to -.5

Figure 24

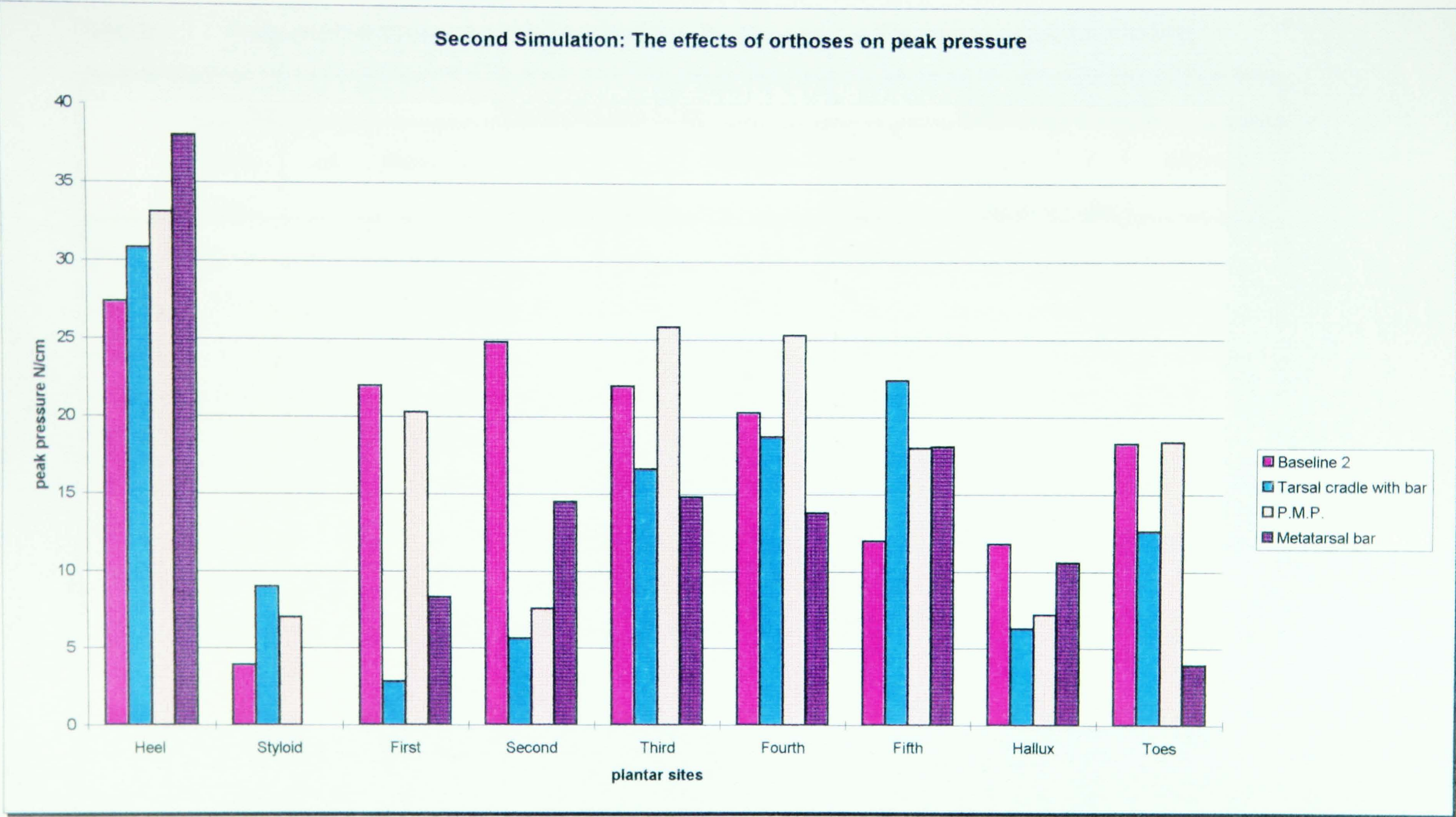


Table 20 **Comparing Peak Pressure at Baseline with Peak Pressure Dependency on P.M.P. and Modified Tarsal Cradle.**

	Baseline		Plantar Metatarsal Pad					Modified Tarsal Cradle				
	Mean	s.d.	Mean	s.d.	< or >	P	95% C.I.	Mean	s.d.	< or >	P	95% C.I.
	Ncm ²				Baseline	Value		Ncm ²		Baseline	Value	
Heel	27.36	3.04	33.09	1.97	>	0.002	-8 to -3.5	30.82	3.04	>	0.02	-5 to -2
Styloid	3.91	0.94	7.00	1.11	>	0.002	-4.52 to -2	9.00	1	>	0.002	-6 to -4
1st. Met	22.00	1.95	20.27	2.15	<	0.02	0 to 3.5	2.82	1.17	<	0.001	17.5 to 20.5
2nd. Met	24.82	1.78	7.55	0.69	<	0.001	15.5 to 19	5.64	0.81	<	0.001	6.5 to 9.5
3rd. Met	22.00	1.98	25.82	1.4	>	N.S.	-2.5 to .5	16.64	1.03	<	0.001	-2.3 to -1.4
4th. Met	20.27	1.2	25.27	1.85	>	0.002	-6.5 to -3	18.73	0.9	<	0.03	0 to 3.5
5th. Met	12.00	1.48	18.00	2.49	>	0.002	-7 to -5	22.36	0.92	>	0.001	-11.5 to -9
Hallux	11.82	2.04	7.18	1.6	<	0.001	3 to 6.5	6.27	1.27	<	0.001	4 to 7
Toes	18.27	1.95	18.36	2.27	>	N.S.	-2 to 1.5	12.64	2.06	<	0.001	4 to 7.5

Figure 25

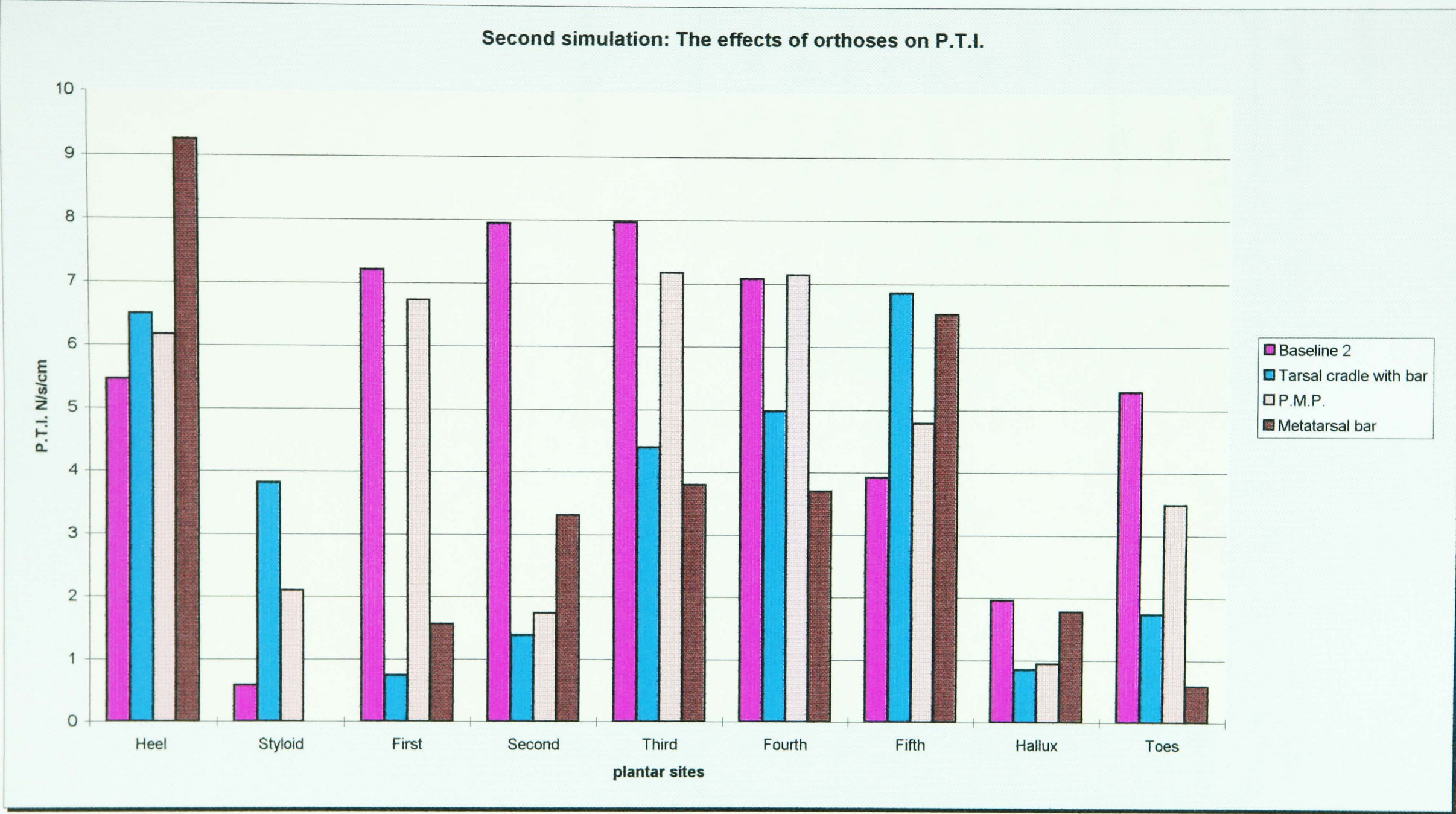


Table 21:

Comparing Baseline 2 Peak Pressure with Peak Pressure Dependency on a Metatarsal Bar.

	Baseline		Metatarsal Bar				
	Mean Ncm ²	s.d.	Mean Ncm ²	s.d.	< or > Baseline	P Value	95% C.I.
Heel	27.36	3.04	38	4.07	>	0.002	7 to 14.5
Styloid	3.91	0.94	*	*	*	*	*
1st. Met	22.00	1.95	8.27	1.42	<	0.001	12.5 to 15
2nd. Met	24.82	1.78	14.45	3.77	<	0.001	7.5 to 13
3rd. Met	22.00	1.98	14.72	4.12	<	0.001	7 to 13
4th. Met	20.27	1.2	13.72	4.47	<	0.001	3.5 to 9.5
5th. Met	12.00	1.48	18.09	4.86	>	0.004	-9.5 to -2
Hallux	11.82	2.04	10.54	5.29	<	N.S.	-2.5 to 5
Toes	18.27	1.95	3.90	1.30	<	0.001	13 to 16

** Data relating to seven events were missing*

Table 22: Comparing P.T.I. at Baseline 2 with P.T.I. Dependency on a P.M.P and a Modified Tarsal Cradle Respectively.

	Baseline		Plantar Metatarsal Pad					Modified Tarsal Cradle				
	Mean	s.d.	Mean	s.d.	< or >	P	C.I.	Mean	s.d.	< or >	P	C.I.
	Nscm ²		Nscm ²		Baseline	Value		Nscm ²		Baseline	Value	
Heel	5.47	0.58	6.17	0.45	>	<0.001	-1 to -.44	6.5	0.53	>	<0.001	-1.3 to -.7
Styloid	0.58	0.26	2.1	0.78	>	<0.001	-2.1 to -.9	3.82	0.25	>	<0.001	-3.4 to -.3
1st. Met	7.21	0.44	6.73	1.03	<	N.S.	-.37 to 1.3	0.75	0.18	<	<0.001	6.2 to 6.7
2nd. Met	7.95	0.59	1.74	0.23	<	<0.001	6.15 to 6.9	1.39	0.22	<	<0.001	6.1 to 7
3rd. Met	7.97	0.71	7.17	0.84	<	<0.001	31 to 1.3	4.4	0.42	<	<0.001	3 to 4.1
4th. Met	7.09	0.77	7.14	1.17	>	N.S.	-.53 to 1.25	4.98	0.41	<	<0.001	1.5 to 2.7
5th. Met	3.92	0.65	4.79	1.05	>	0.009	-1.58 to -.14	6.86	0.55	>	<0.001	-3.5 to -2.7
Hallux	1.96	0.36	0.94	0.35	<	<0.001	.67 to 1.36	0.85	0.32	<	<0.001	.8 to 1.5
Toes	5.3	0.67	3.49	0.61	<	<0.001	-2.3 to -1.4	1.74	0.34	<	<0.001	3.1 to 4

Table 23: Comparing P.T.I. at Baseline 2 with P.T.I. Dependency on a Met. Bar.

	Baseline		Metatarsal Bar				
	Mean Nscm ²	s.d.	Mean Nscm ²	s.d.	< or > Baseline	P Value	C.I.
Heel	5.47	0.58	9.27	1.00	>	<0.001	-4.6 to -3
Styloid	0.58	0.26	*	*	*	*	*
1st. Met	7.21	0.44	1.55	0.38	<	<0.001	5.2 to 6.2
2nd. Met	7.95	0.59	3.30	1.09	<	<0.001	3.6 to 5.5
3rd. Met	7.97	0.71	3.79	1.19	<	<0.001	3.25 to 5
4th. Met	7.09	0.77	3.49	1.15	<	<0.001	2.8 to 4.5
5th. Met	3.92	0.65	6.51	1.71	>	0.001	-3.8 to -1.2
Hallux	1.96	0.36	1.77	1.14	<	N.S.	-.65 to 1.04
Toes	5.3	0.67	0.57	0.24	<	<0.001	4.3 to 5.1

** Data relating to seven events were missing*

Test-Retest Results

At the close of the investigation, one further walk was undertaken wearing the Vizianagram sandal without any modifications. In this manner the procedure for collecting baseline data was repeated. Data relating to peak pressure values from the last walk were compared with data relating to peak pressure values from the first walk. If the values were found to have been different, a systematic source of bias may have been indicated. The reliability of the method would then have been questionable.

Table 24: Test-Retest

Site	First Walk n = 11		Last Walk n = 11		P Value (two tailed)	95% C.I.
	Mean Ncm ²	S.D.	Mean Ncm ²	S.D.		
Heel	29.64	2.12	28.45	4.46	0.85	-3.5 to 2.5
Styloid	4.36	0.5	4.45	0.5	0.70	-.5 to .5
1st. Met.	44.27	3.16	46.36	2.54	0.12	-.5 to .5
2nd. Met	16.73	1.01	15.36	3.29	0.25	-4 to .5
3rd. Met	11.09	1.87	10.82	1.99	0.58	-2 to 1
4th. Met	10.73	2.2	10.18	1.53	0.22	-.5 to 1.5
5th. Met	5.55	2.16	6.36	1.43	0.44	-1.5 to 3.5
Hallux	23.82	1.08	24.36	3.29	0.38	-3.5 to 1.5
Toes	13.36	.5	13.09	0.70	0.16	*

* C.I. is not calculated where there are fewer than four differences.

3.3.1 PRESSURE TIME INTEGRAL AND PEAK PRESSURE

Relationships between PTI values and peak pressure values were tested. Baseline data, followed by test condition data, were analysed using Pearson's correlation coefficient.

Peak Pressure vs. PTI / Baseline 1:	$r = .96$	$P < 0.0001$	CI = 0.82 to 0.99
Peak Pressure vs. PTI / M.T.C.	$r = .91$	$P = 0.0005$	CI = 0.65 to 0.98
Peak Pressure vs. PTI / Cobra Pad	$r = .81$	$P = 0.007$	CI = 0.33 to 0.95
Peak Pressure vs. PTI / Baseline2:	$r = .87$	$P < 0.0002$	CI = 0.48 to 0.97
Peak Pressure vs. PTI / Met.Pad	$r = .89$	$P = 0.001$	CI = 0.54 to 0.97
Peak Pressure vs. PTI / 2 M.T.C.	$r = .90$	$P = 0.0007$	CI = 0.61 to 0.98
Peak Pressure vs. PTI / Met. Bar	$r = .95$	$P = 0.0002$	CI = 0.76 to 0.99

(P values indicate the probability of a relationship different from no relationship)

These results demonstrate that changes in peak pressure are related to changes in PTI. A consequence of this finding is that inferences drawn from peak pressure findings may also be assumed to be applicable to PTI. On only one occasion was it found that there was no difference when compared on peak pressure, but that a reduction in PTI was significant (Baseline 2 versus P.M.P. at the toes.). One other event (at the 2nd MTH) demonstrated that peak pressure under Baseline 1 conditions was significantly less than with the Cobra Pad. PTI at this site was not found to be different. On these two occasions it may be inferred that the test conditions affected the duration of pressure applied: i.e. the pressure was no different (Baseline 2) or greater (Baseline1) but the duration of pressure applied was less than may have been expected.

3.3.2 MODIFIED TARSA CRADLE (M.T.C.)

The rationale supporting the use of the M.T.C. is detailed in section 2.1.9. In this test it was applied, primarily, to deflect pressure from the simulated area of vulnerability and to redistribute it to other, stable areas of the foot. It may also have acted to restrain hypermobility by attenuating the effects of subtalar pronation. There are two

primary effects of the M.T.C. in this application. As the calcaneus everts, force is applied to the medial plantar posterior process of the cuboid causing axial rotation of the cuboid with associated hypermobility of the lateral column. Support beneath the cuboid should resist rotation and assist in stabilising the fourth and fifth metatarsals. With the adduction and plantarflexion of the talus, the navicular is destabilised and the medial column becomes hypermobile. Support beneath the talonavicular joint and at the sustentaculum tali may assist in the stabilisation of the foot against evortory forces.

The M.T.C. fills the concavity of the medial arch, thereby palliating the soft tissue attachments and joints. Supporting the architecture of the foot enhances first ray function.

The results demonstrated a highly significant difference in peak pressure at the first MTH. Mean peak pressure of 44.27 N/cm^2 was recorded beneath the first metatarsal wearing Vizianagram sandals whereas with the M.T.C. the mean peak pressure recorded was 13.64 N/cm^2 . This represents a 69.2% (30.63 N/cm^2) reduction of peak pressure at the 1st MTH. It appears therefore, that in its function to deflect pressure, the M.T.C. was successful.

Although the total peak pressure over all regions measured using the M.T.C. was higher (159.55 N/cm^2 with the Vizianagram sandal and 192.6 N/cm^2 with the M.T.C.) this difference was not statistically significant. However, on balance, it would appear that 40% of the reduction in peak pressure appears to have been accommodated by other structures (metatarsal shafts, medial arch and the device). The greater proportion of redistributed pressure appears to have been achieved by increasing the loading at the MTHs and the toes.

The most notable effect, secondary to the reduction in peak pressure at the first MTH, was the difference in loading of the MTHs under alternative conditions. The second and lateral MTHs were aligned in the same plane. If kinematic variables did not change, it would have been reasonable to suggest that the expected increments in

peak pressure at these sites would have increased proportionately, relative to baseline recordings. This was not found to be so.

Baseline 1 recordings demonstrated a gradual increase in peak pressure values from the lateral aspect to the first MTH. Using the M.T.C., a converse effect was demonstrated: i.e. the highest peak pressure values were recorded at lateral sites with a gradual reduction in values medially. The recording beneath the 5th MTH was not as high as that beneath the fourth MTH. This was probably because the fifth metatarsal is more mobile than the fourth and was able to respond to ground reaction by dorsiflexing further than the fourth metatarsal.

Whilst this evidence of increased lateral loading does suggest that the consequences of excessive subtalar pronation were affected, it does not signify sound foot function. Indeed the indication is that the M.T.C. may have caused the foot to invert further than its optimal frontal plane position. Ground reaction would impose an evertory force on the forefoot which would have been opposed by the medial elevation of the foot and the effects of external rotation of the tibia. As a consequence loading would have been concentrated laterally. The foot does not appear to have been inverted to excess. Had it been so, ground reaction forces would have dorsiflexed the fifth metatarsal to the full extent of its range of motion. As a consequence, compressional stress would have been excessive causing higher peak pressure beneath the fifth MTH than the fourth MTH.

A notable feature was the highly significant reductions in peak pressure and PTI beneath the hallux and an increase in the same values beneath the toes. It may be that the elevated digital pressures are an indication of a functional compensatory mechanism to increase load bearing area and thereby reduce pressure on the MTHs. A more likely alternative is that the increased pressure may indicate demands on digital function for propulsion.

The reduced peak pressure and PTI values beneath the hallux and the 1st MTH may indicate that the medial aspect of the foot was too elevated to effect competent first

ray function and propulsion from the hallux. It must be considered however that the subject did not have a pathological foot.

In a clinical context, an M.T.C. of the type under investigation may be indicated for an individual with a congenital or acquired plantarflexed first ray deformity. Assuming such conditions, the M.T.C. may cause the foot to function differently. I would postulate that there could be two interrelated primary effects. The M.T.C. could act to stabilise the foot and bring the second and lateral MTHs into ground contact without the forced dorsiflexion of the 1st MTH.

3.3.3 THE COBRA PAD

The rationale supporting the use of a cobra pad is that it should attenuate the effects of aphasic or excessive subtalar pronation. With the provision of a heel meniscus an inventory lever arm may effect a sufficient inventory moment to impede the effects of medial loading of the calcaneus. Support of the medial arch palliates the structure and enhances the arch mechanism by assisting to maintain its configuration. By supporting the talonavicular joint the adduction and plantarflexion of the talus and eversion of the navicular is resisted. By reducing the associated hypermobility, it enhances foot function and, consequently, the distribution of forces. One effect should be a limitation in the development of foci of high pressure.

The results suggest that the hypothetical construct outlined above was supported. Of principal interest was that the peak pressure beneath the 1st MTH was reduced by 42%. This was achieved without incorporating a deflective component. The reduction may have been effected by the greater load bearing area facilitated by the cobra pad. However the highest peak pressures were likely to have been recorded after heel lift when the cobra pad would no longer have an influencing effect. This suggests that the cobra pad assists foot function after it is actually loaded, perhaps by improving midstance preparation for heel lift.

Although significantly reduced when compared with Baseline 1 readings, the greatest

peak pressure was still recorded beneath the 1st MTH. The readings at other MTH sites, however, are noteworthy. Peak pressure readings, relating to sites beneath all other MTHs, suggest a more even distribution of metatarsal load bearing function compared with Baseline 1.

In structure and function, the 1st. MTH is better facilitated to accommodate greater loads. It is frequently assumed that because the 2nd MTH has a smaller contact area it would be more vulnerable to higher peak pressure than the 1st MTH. This observation has been used to explain why higher 2nd MTH peak pressures are commonly found. It may be, however that the size of the MTH and the relative rigidity of the second metatarsal only compromise the 2nd MTH when the first ray does not function effectively. (This was discussed in section 2.7.2.) It is my contention that if the kinematic function of the foot is correct, excessive overloading of the second metatarsal would be avoided.

3.3.4 THE SECOND SIMULATION

The second simulation mimicked the common consequence of pathomechanical foot function which results in overloading the second MTH. Huson (1991) postulated that the second metatarsal acts as a pivot for a forefoot twist. If this suggestion is correct the soft tissue supporting the second metatarsal should demonstrate anatomical adaptations to accommodate shearing stress. Such adaptations should differentiate the site from other forefoot sites. This does indeed appear to be so. The relative immobility of the second metatarsal, and its peculiar anatomical adaptations, suggest that excessive compressional forces are likely to be more directly implicated in stress related trauma. However, there will be a threshold beyond which such anatomical modifications will demonstrate fatigue. An implication is, therefore, that as stated earlier, tissue stress will not be related to vertical stress in isolation.

3.3.5 MODIFIED TARSAL CRADLE 2 (M.T.C.2)

The M.T.C.2 assessed for affecting peak pressure and PTI at the second MTH (second simulation) differed from the M.T.C. used for the first simulation. The M.T.C.2 device did not incorporate a forefoot extension. The dimensions extended to the area immediately posterior to the MTH formula. At the distal edge the device incorporated a metatarsal bar. In all other respects the device respected suggested dimensions for a custom made tarsal cradle. An extension similar to that of the M.T.C.1 could have been used. Instead of incorporating a medial wing, a 'U' shaped cut out would have been an alternative. It was decided however that a broader perspective of principles would be demonstrated by incorporating a metatarsal bar. Many leprosy impaired feet, of long duration, will present with bone absorption or similar disorganised features associated with forefoot ulceration. Some patients present with multiple ulcers. For such as these the M.T.C.2 may be a sound management option.

The M.T.C. 2 is indicated when the desired effect is to enhance the stability of the foot and to reduce the weightbearing demand on the forefoot. Whilst the tarsal cradle effect is designed to improve stability the metatarsal bar shifts the treadline posteriorly. In so doing the MTHs are elevated and pressure is redistributed to the metatarsal shafts. Whether these objectives were met under the experimental conditions is difficult to conjecture.

It may be that to demonstrate a "rocker" effect the device would need to be worn on a less yielding surface than 8mm of 18 shore rubber. Nevertheless, the site of particular interest was the second MTH (the site of simulation) where, compared with Baseline 2, the reduction in peak pressure was highly significant. A similar finding was recorded at the first MTH. The values recorded at these two sites represent the lowest peak pressure recordings under the medial MTHs of any experimental condition.

Mean peak pressure of 24.82 N/cm^2 was recorded beneath the second metatarsal

wearing Vizianagram sandals whereas with the M.T.C. 2 the mean peak pressure recorded was 5.64 N/cm^2 . This represents a 77.27% (19.18 N/cm^2) reduction of peak pressure at the second MTH. There were further significantly lower peak pressures at all locations except the styloid process and the fifth MTH which were both significantly higher than comparable baseline locations. These findings may have indicated that the anterior lateral edge of the device may have extended too far distally. The result of such a scenario would be that the 5th MTH would rest on the bar, rather than distal to it. Alternatively, the device may have caused the foot to invert excessively thereby exposing the 5th MTH to excessive compression. A similar change in loading pattern to that recorded for the other antipronatory devices was recorded; i.e. increased weight bearing laterally suggesting a redirecting of the centre of force. It appears that the demand on the MTHs was generally alleviated. However, the effect of the bar toward the lateral aspect of the plantar surface may have been to increase the area of weightbearing around the MTHs, thereby reducing pressure, rather than to shift the tread line posteriorly.

A major effect of toe function is the expansion of the weight bearing area with a consequent reduction of pressure at the MTHs. The significant reduction in peak pressure at the toes suggests that there was a general increase in the weight bearing area (this effect was marked when the metatarsal bar was used). Alternatively, the elevation of the metatarsals may have compromised toe function and reduced the capability for digital stabilisation of the metatarsals. Digital redundancy would be reflected as a reduction of pressure beneath the toes.

3.3.6 THE METATARSAL BAR

The rationale for applying a metatarsal bar is that, theoretically, it shifts the treadline posteriorly providing an alternative pivot to relieve the MTHs. As the bar elevates the metatarsals, pressure from the MTHs is redistributed to the bar and the metatarsal shafts. As with the M.T.C. 2 this effect may have been confounded by the depth and shore of the micro-cellular rubber insole.

Although significantly less than the Baseline 2 recordings (except at the fifth MTH) the recordings relating to the metatarsal bar demonstrate a loading pattern similar to that of the Baseline 2 pattern. Fitting immediately posterior to the metatarsal formula the effect of the bar may have been to increase the loadbearing area thereby reducing peak pressure at the MTHs. However, consideration of the effects of toe loading does suggest that the metatarsals were elevated. Peak pressure recordings for the toes under both M.T.C.2 and metatarsal bar conditions were the lowest recorded (toe peak pressures with the metatarsal bar were recorded as 4N.cm^2 compared with 18.27 N.cm^2 recorded at baseline).

The increase in pressure at the fifth MTH was perhaps due to incorrect positioning of the device. The lateral aspect of the bar may have been situated beneath the MTH thereby exacerbating the effect of loading. This is an important feature as it demonstrates the requirement for fastidious positioning of devices.

3.3.7 THE METATARSAL PAD

It is postulated that the application of a metatarsal pad with a cut away has the effect of deflecting pressure from the area accommodated by the cut away. Pressure is accordingly redistributed to the other metatarsals and is partially accommodated by the device.

The loading pattern demonstrated by the results does support the theory. There was a highly significant reduction of peak pressure at the second MTH (17.3 N/cm^2) with an increase in peak pressure beneath the lateral MTHs. There was however a decrease in peak pressure at the first MTH which, although small, was significant ($P = 0.02$). If the device was positioned such that the antero-medial border lay posterior to the MTH, a similar effect to that recorded for the metatarsal bar would have been recorded. A slight posterior displacement of the device may explain the unexpected reduction in peak pressure at the first MTH.

3.4 DISCUSSION

The principal aim of this investigation was to investigate the suggestion that leprosy sandals with customised podiatric orthoses do effect a reduction of peak pressure and PTI when compared with the same sandals without podiatric orthoses.

A limitation of the findings reported is that the effects that were demonstrated only reflect simulated conditions. Kinetic variables associated with pedal pathologies will be dependent on kinematic, anatomical and physiological factors that did not affect the results of this investigation (Cavanagh *et al.* 1991a, 1991b, Zhu *et al.* 1993) A further limitation is that the results reflect the immediate effects of orthotic intervention. No indication is given, therefore, of the effects of time on the mechanical properties of the materials used, or of device integrity after a period of wear.

The strength of the findings reported is also limited because no investigations have been reported with which direct comparisons could be made. This difficulty is further complicated because reported results, where diverse systems have been used, frequently demonstrate divergence rather than similarity. (Lord 1981). It appears, however, that relationships (eg. findings relating to different types of footwear and loading patterns), rather than absolute values, can be compared (Hughes *et al.* 1993). Such comparisons will be made, where applicable, in the course of this discussion.

3.4.1 METHODOLOGICAL ISSUES

The reliability of a system essentially relates only to its ability to reproduce similar results under the same conditions, as such reliability does not always infer validity. Part of the reason that findings are not often replicated may be that insufficient consideration is given to the variable affects of kinematic joint function on sub pedal pressure. Subjects presenting with aphasic subtalar pronation, for example, may demonstrate higher peak pressures beneath the second metatarsal head than other subjects. Until such time as kinetic findings can be correlated with kinematic joint

function (particularly of the rearfoot in relation to the forefoot) it is the authors contention that there will not be repeatable findings to provide valid standards. The author questions any method that purports to describe values for normal feet where normalcy is not defined in terms of kinematic foot function.

It has been demonstrated that intersubject walk to walk variability does vary more widely than intrasubject variability (Hughes *et al.* 1991, Akhlaghi *et al.* 1993). Based on the findings of Hughes *et al.* (1991) it is reasoned that studies in which the subject is his/her own control, will yield more reliable findings than intersubject comparisons. Using the Gaitscan system, Akhlaghi (1993) recorded that intrasubject variations in peak pressure values, at a specified site, recorded over 10 walks was as great as 73% from the mean value. They also recorded variations of 66% from mean values within individual walks. However, no attempt was made to establish or to standardise cadence which has been shown to affect force related parameters (Zhu *et al.* 1993, Lord and Hosein 1994). Whereas the validity of foot ground interaction recordings is greater where cadence is not standardised, kinematic variables must be controlled where the effects of independent variables are to be assessed.

Akhlaghi *et al.* (1993) demonstrated that, in their trial, there was a medio-lateral variation in peak pressure distribution that presented a cyclical pattern with periods varying between two and five steps (i.e. that pressure distribution varied from medial to lateral over one or more steps during each trial.). This may contribute toward explaining the diverse findings of others who tried to establish patterns of forefoot loading. Of more direct relevance to this investigation however is that this finding confirms the requirement that measurement should be recorded over sequential footsteps. A further advantage of sequential recording is that the question of which step to record: i.e. mid-gait (Hughes *et al.* 1991), first step (Cavanagh and Ulbrecht 1994), or second step (Meyers-Rice *et al.* 1994), becomes less of an issue. Other investigators, using in-shoe systems, have used data relating to all steps (Zhu *et al.* 1991, Chang *et al.* 1994) whilst some declared that they only included data generated on the establishment of steady gait (Akhlaghi *et al.* 1993, Hughes *et al.* 1993).

Relating to this investigation, a decision as to when data collection should commence was based on the consideration of findings reported by Meyers-Rice *et al* (1994). Other investigators had established that there was a correlation between walking speed and plantar pressure (Morlock and Mittlemeir 1992). The established mid gait method of data collection would consequently represent plantar pressures higher than those that would be recorded for an initial step. Meyers-Rice *et al.* (1994) sought to determine whether the reliability of pressure data relating to the midgait method could be reflected in methods where data was collected after one or two steps. Their findings suggest that data collected after two steps was representative of data describing mid gait events. It was decided therefore that data would be collected after the second step and would culminate three steps before the end of the walk.

3.4.2 NORMAL VALUES

Due to the marked methodological and technological differences alluded to earlier, standard normal values for regional plantar pressures are elusive. Reports of peak pressures during normal barefoot walking range from 98 to 850 kPa, (Dhanendran *et al.* 1978, Betts *et al.* 1980, Soames 1985, Patil *et al.* 1986, Patil and Srinivasan 1987, Bransby Zachary 1990) whilst variations in findings relating to normal walking in shod populations range from 90 to 550 kPa (Dhanendran *et al.* 1978, Soames *et al.* 1982, Hughes *et al.* 1987, Zhu *et al.* 1991). The method by which normal values for a defined population can traditionally be established is to consider the mean value plus or minus two standard deviations. This method was used by Cavanagh and Ulbrecht (1991b) to demonstrate normative peak pressure values for non-diabetic elderly men. However on the admission of the same authors in a later publication, this method can be misleading in the context of plantar trauma to the neuropathic foot (Cavanagh and Ulbrecht 1994). The reason for the anomaly is that the "normal" range in the forefoot (as defined above) included values considered high enough to cause ulceration in neuropathic feet (500kPa. using an EMED platform). It would be more logical to establish a threshold above which there exists a greater potential for trauma in any given population.

The findings of other researchers may validate the principles upholding the therapeutic rationale for orthotic treatment. There are, however, fundamental differences between this investigation and others that have been reported. As indicated earlier, there is a relative dearth of quantitative research describing the effects of foot orthoses. Of the research that has been published only that of Barrow *et al.* (1992) and Lord (1994) describe weight bearing effects of custom made orthoses.

A study by Bradley and Balder (1986), in which the effects of orthoses on areas of simulated high pressure was reported, lacks detail. Bradley and Balder's study examined the dependency of peak force (effected by simulated callus) on customised insoles. They reported that peak force was reduced by an average 50% using 'U' plantar metatarsal pads constructed from different materials. Unfortunately insufficient data was presented to correlate the findings of this study with those of Bradley's study.

Hayda *et al.* (1994) reported a quantitative assessment of the effect of metatarsal pad positioning on plantar pressure. Their conclusions are spurious, there was no statistical analysis of the data which had, in any event, been misinterpreted (pressure was presented as N units).

Comparison with the findings of Barrow *et al.* (1992) is approached with caution. Their approach (taped modified insoles to the feet of subjects) may not reflect events at the foot shoe interface. (Soames [1985] recorded differences when comparing shod and barefoot subjects.) Furthermore, the data Barrow *et al.* gathered was generated by each subject applying three steps on a pedobarograph and is therefore unlikely to demonstrate characteristics generated by sustained walking. The pilot study reported by Lord and Hosien (1994) more closely resembles this investigation in that individually moulded inserts were evaluated using the F Scan gait analysis system. The moulded inserts Lord and Hosien (1994) used were designed to redistribute load away from the metatarsal area. Moulded to the shape of the foot the devices they

used also incorporated a "rocker" element to facilitate "roll off" from a position posterior to the MTHs. The devices all displayed a "well-defined arch". These devices were compared with flat PPT inserts 6mm thick. Wearing the PPT inserts, all subjects demonstrated high peaks of pressure beneath the first MTH with a second peak beneath the second or third MTH. The mean maximum peak pressure they recorded using the flat inserts was 305 kPa (30.5 N/cm²). This was significantly higher than the 216 kPa (21.6 N/cm²) using the moulded insert. Comparing these findings with the M.T.C. 2 used in this study, their results demonstrate the same trend if not the same magnitude.

Barrow *et al* (1992) compared the efficacy of different insole materials commonly used for custom made devices. They examined the effects of custom made insoles incorporating 'U' cut aways to deflect pressure from high pressure areas. Compared with barefoot values all insoles reduced pressure. The reductions in peak pressure they recorded beneath the second MTH averaged 75.5 kPa (7.5 N/cm²) (using new and old insoles). This finding was not as great as the 13.7 N/cm² reduction recorded using the plantar metatarsal pad. However they demonstrated that the subject with the highest baseline peak pressure value demonstrated a greater reduction (175 kPa or 17.5 N/cm²). Three of seven subjects in their study demonstrated reductions in peak pressure greater than 100 kPa. These findings are similar to the findings recorded in this study.

The findings of McLauchlan *et al.* (1994) are not in agreement with the findings of this study. However, it is difficult to draw a comparison due to methodological differences. McLauchlan *et al.* could not demonstrate that plantar metatarsal pads with 'U' cut aways could consistently reduce peak pressure. They found that values differed between the right and left foot. Whilst they reported that the device significantly reduced pressure at the second MTH of the left foot this finding was not repeated on the right foot. Had they considered individual variations that would determine the precise site of highest peak pressure a more conclusive result may have been recorded.

Studies that have examined the effects of bespoke metatarsal pads (Holmes and

Timmerman 1990, Chang *et al.* 1994, McLauchlan *et al.* 1994) are broadly consistent in the findings that have been reported. The findings relating to metatarsal pads cannot be compared with findings from this study as the design and application of such devices dictate a different mode of action. A relevant finding reported by Chang *et al.* (1994), however, is that by loading the metatarsal shaft area there was a slight but significant decrease in peak pressure values at the forefoot. By increasing the time to contact, force, and consequently pressure, is reduced. A conclusion drawn by Chang *et al.* (1994) was that the redistribution of plantar pressures relates to foot size, anatomical foot configuration, and pad location as much as it does to dimensions of the device. This is a significant observation as it exemplifies the rationale for custom made devices.

CHAPTER 4

THE IMPLEMENTATION AND SUSTAINABILITY OF A PODIATRIC REGIMEN

INTRODUCTION

At the March 1994 assessment it became apparent that the experimental group had benefited from the provision of orthoses. In accordance with ethical considerations, it was accepted that, following ulcer assessment, those subjects who had constituted the control group would then be supplied with orthoses. An advantage of this development was that it presented an opportunity for an assessment of the implementation of the programme.

4.1 AIMS

This aspect of the study aims to demonstrate whether knowledge and skills were successfully transferred and whether the implementation of practice was sustainable. Continual assessment of trial subjects also provided data to assess the long term efficacy of the treatment.

This chapter will address the following:

1. Teaching and orthotic supply methods.
2. Sample details and methods of statistical analysis.
3. Data describing and analysing assessment findings during the period from March 1994 to September 1995. This data will be used to augment earlier findings relating to efficacy.
4. The effects of orthoses prescribed and supplied by H. Cross compared with the effects of orthoses prescribed and supplied by A. Dey.
The implementation of the service will be evaluated on the strength of these findings.
5. Data collected in January 1995 compared with data collected during

November and December 1995. Findings, augmented by observations from field notes, will be used to identify issues relating to sustainability.

6. Discussion of results.

4.2 METHOD

4.2.1 THE IMPLEMENTATION OF KNOWLEDGE AND SKILLS: JULY TO SEPTEMBER 1993

Over a four week period V. Kulkarni (physiotherapist) had received personal daily tuition from G. Rendall. The aim of this instruction was to resource the physiotherapy department with current knowledge of pedal mechanics. The tuition presented to V. Kulkarni by G. Rendall was based on material currently used in British curricula for the instruction of undergraduate podiatry students. Centred around the theme of function and dysfunction of the foot, topics included functional pathology, pathological stresses and tissue response to stress¹². Examination of the foot and procedures for the measurement of relevant parameters was taught by the author. This knowledge base was complemented by imparting skills, supported by appropriate theory, to the physiotherapy technician and a prosthetics technician. On completion of training, therefore, the physiotherapy department was resourced with a professional with a theoretical base and two technicians with more basic theory applied to practice.

The instruction given to A. Dey (physiotherapy technician) and R. Karunakaran (prosthetics technician) was based on the following criteria:

Objectives:

1. Knowledge

Technicians should be able to:

- (a) Identify key bony landmarks and joint positions on the foot.

¹² V.Kulkarni was presented with a copy of *Common Foot Disorders* (Neale and Adams 1992) which is considered an essential reference text.

- (b) Evaluate ulcers.
- (c) Apply appropriate principles of cushioning, redistribution and functional control.
- (d) Recognise indications and contra-indications for plaster casting and orthotic treatment.
- (e) Give appropriate advice to patients.

2.Skills

Technicians should be able to:

- (a) Systematically examine the foot.
- (b) Develop recording systems.
- (c) Demonstrate machine skills to execute bevelling (external round and internal round edges).
- (d) Construct and fit
 - 1. Plantar Metatarsal Pads
 - 2. Tarsal Platform
 - 3. Tarsal Cradle
 - 4. Cobra Pad
 - 5. Metatarsal Bar
 - 6. Metatarsal Shaft
 - 7. Heel Wedges
 - 8. Combination Pad
- (e) Apply principles of strapping appropriate for the manufacture of a removable device.

3.Integration

Technicians should be able to:

Integrate knowledge and skills to develop a principles based approach to the provision of orthoses as an adjunct to existing therapy.

Under supervision A. Dey constructed a number of devices and observed as the author prescribed and supplied all the devices manufactured for the Experimental group subjects.

By the 15th of September 1993 instruction was complete. All experimental group subjects had been supplied with orthoses and had been reviewed one week after supply. The ulcer assessments that had been conducted in July were repeated in September. Staff at Dr Bandorawalla Leprosy Hospital, appeared to be confident and the author was satisfied that an adequate level of competency had been reached.

4.2.2 SUPPLY OF ORTHOSES: MARCH 1994

All subjects, wearing sandals, were supplied with new footwear in March 1994. the author renewed or transferred all orthoses that had been prescribed for subjects who had constituted the Experimental group.

Orthoses for subjects that had constituted the Control Group were prescribed and supplied by A. Dey without consulting the author. Record of all orthoses supplied to this group was maintained by A. Dey. All subjects, with orthoses, were subsequently examined by the author to ascertain the safety of orthoses supplied. None of the orthoses supplied by A. Dey were considered inappropriate but four devices were considered to have been incorrectly positioned. These cases were brought to the attention of A. Dey who subsequently repositioned the devices satisfactorily.

4.2.3 SAMPLE DETAILS

At the March 1994 assessment 31 subjects from the Experimental group and 32 subjects from the Control group presented for assessment. Between March 1994 and September 1994 three male subjects dropped out from the Experimental group and three subjects (2 male and 1 female) dropped out from the Control group¹³.

Following the March 1994 assessment, subjects from the Experimental group were allocated to Group C (subjects who had been supplied with orthoses by H.Cross). Subjects from the Control group were allocated to Group D (subjects supplied with orthoses by A. Dey in March 1994).

Table 25:
Subjects Continuing in the Programme From March 1994 to September 1994

Group	Individuals			Feet	Sites of interest*
	Mean Age	Male	Female		
C	37.1 (S.D. 10.2)	24	4	30	35
D	43.3 (S.D.10.6)	21	8	32	35

* Includes sites on the plantar aspect of the foot that were ulcerated at the onset of the programme (July 1993), ulcers at assessments during the period of interest, and ulcers that developed at alternative sites subsequent to orthotic prescription¹⁴.

13. When these subjects failed to respond to requests to attend for assessment, further investigation ascertained that five had left the area and that one had become house bound. The house bound individual was an elderly female with a healed ulcer. She was unwilling to participate further. Her decision was respected and she was excluded from the investigation.

14. One incident between March and June and one further incident between June and September. Both events occurred in Group C.

4.3 RESULTS

Figures 26 and 27 demonstrate changes in ulcer area, in Group C and Group D respectively, at successive assessments from March 1994 to to September 1994. Analysis of these results follows.

Group C: changes in ulceration from March 1994 to January 1995

Figure 26

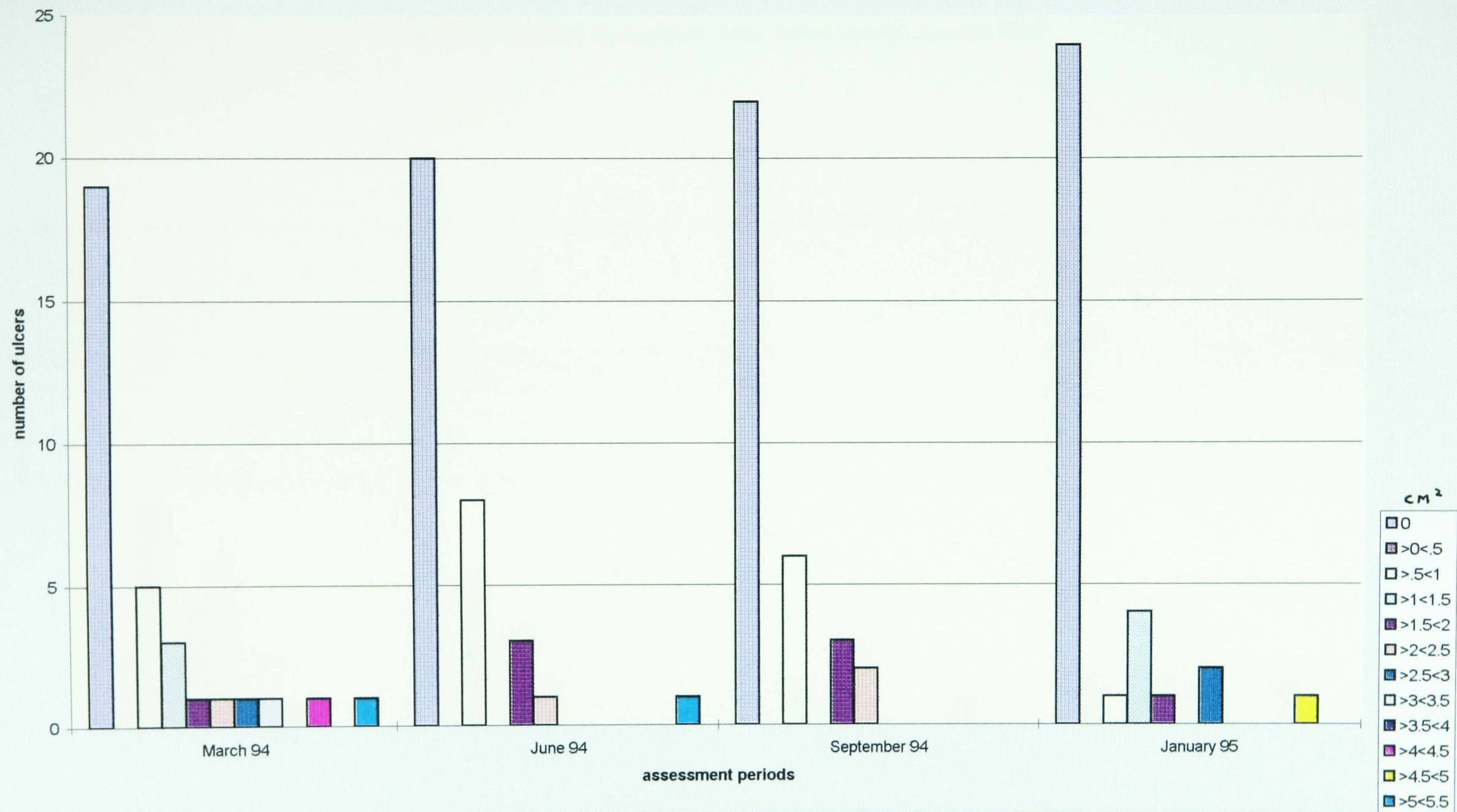
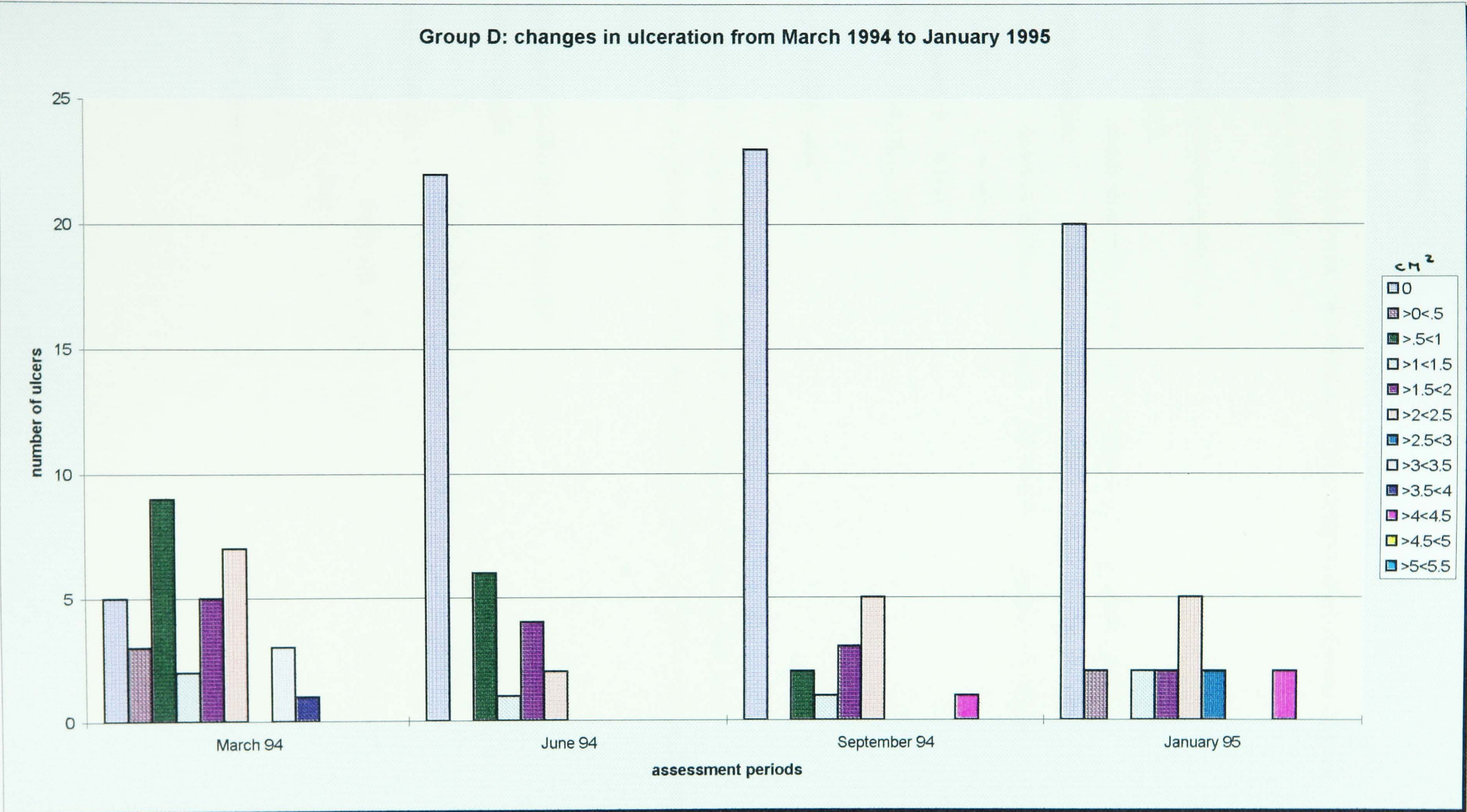


Figure 27



4.3.1 MARCH 1994

At the March 1994 assessment 58% of Group C ulcers had healed whereas 14% of Group D ulcers had healed.

Comparison of Groups in March 1994

Group C ulcers

n = 33 mean ulcer area = 0.81 cm² S.D.= 1.33 Median = 0cm²

Group D ulcers

n = 34 mean ulcer area = 1.37cm² S.D.= 9.1 Median = 1.18cm²

U = 332.5 U' = 789.5

Two Tailed P = 0.002

95% C.I. = -1.18 to -0.01

4.3.2 JUNE 1994

By June 1994 (in the third month after Group D had also been supplied with orthoses) 60% of the ulcers in Group C had healed and 62% of ulcers in Group D had healed.

Comparison of Groups in June 1994

Group C ulcers

n = 33 mean ulcer area = .59cm² S.D.= 1.19 Median = 0

Group D ulcers

n = 34 mean ulcer area = .52cm² S.D.= .88 Median = 0

U = 581.5 U' = 540.5

Two Tailed P = 0.9

95% C.I. = 0 to 0

Three months after Group D had been supplied with orthoses the difference between the two groups was no longer significant. This finding does suggest that the orthotic intervention administered by the physiotherapy department was associated with restoring homogeneity between the two groups. However, to compare the effects of the orthoses supplied by the physiotherapy department with those supplied by the author, more equitable baseline data was identified.

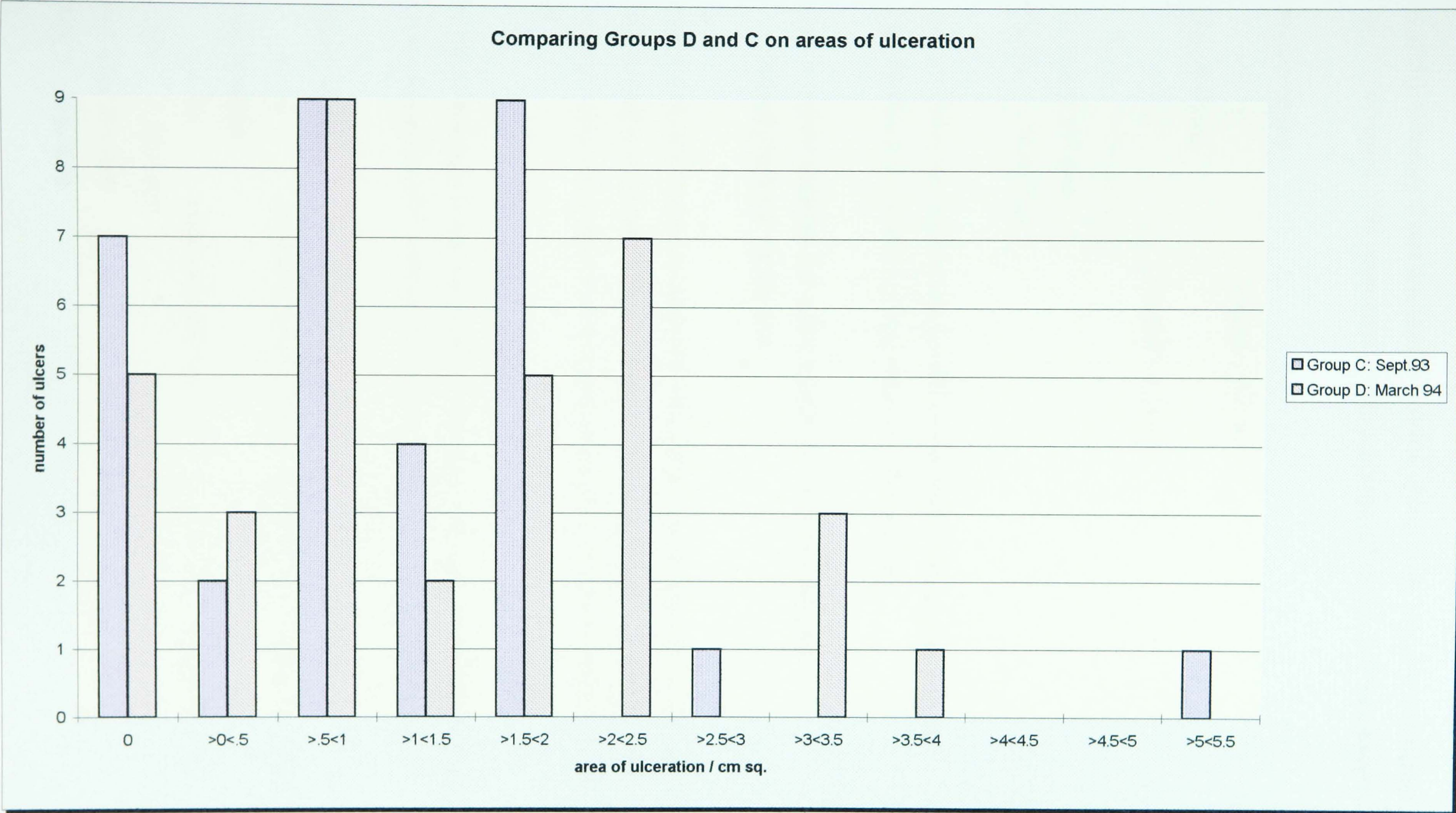
Ideally Group D should have been matched with a similar group both of which would have been prescribed with orthoses simultaneously. This could not be accomplished. It was decided that Group D data would be compared with earlier findings relating to Group C.

At the onset of the trial, when Group C were supplied with orthoses, the ulcer dimensions in Group C were significantly greater than those recorded for Group D in March 1994 (i.e. when Group D were supplied with orthoses). To match the two groups on ulcer area, assessment data relating to Group D in March 1994 most closely resembled Group C data recorded in September 1993. (I.e. 4 to 6 weeks after Group C had been supplied with orthoses.) (See Fig. 28)

At the September 1993 assessment, of the 33 sites of interest in Group C, 27 presented with unresolved ulcers. The mean area of all sites was 1.10 cm^2 (S.D. 1.08).

At the March 1994 assessment, of the 34 sites of interest in Group D, 29 sites presented with unresolved ulcers. The mean area of all sites was 1.37 cm^2 (S.D. 1.02).

Figure 28



The **Mann-Whitney U test** was used to compare area of ulceration between Group C (at the September 1993 assessment) and Group D (at the March 1994 assessment).

Group C ulcers

n = 33 Median = .98 cm²

Group D ulcers

n = 35 Median = 1.18 cm²

U = 464.5 U' = 657.5

Two Tailed P = 0.16

95% C.I. = -.79 to -0.19

It was noted that although the baseline differences between the groups were not significant Group C did have a greater number of healed ulcers.

4.3.3 A COMPARISON OF LIKE GROUPS AFTER SIMILAR DURATION OF THERAPY

Group C data collected at the December 1993 assessment were compared with Group D data collected at the June 1994 assessment. Thus both groups, matched for ulcer area, were compared on ulcer area following similar periods of intervention (see Fig. 29).

The **Mann-Whitney U test** was used to compare area of ulceration between Group C (at the December 1993 assessment) and Group D (at the June 1994 assessment).

Group C ulcers

n = 33 mean ulcer area = .82 cm² S.D.= 1.33 Median = .78 cm²

Group D ulcers

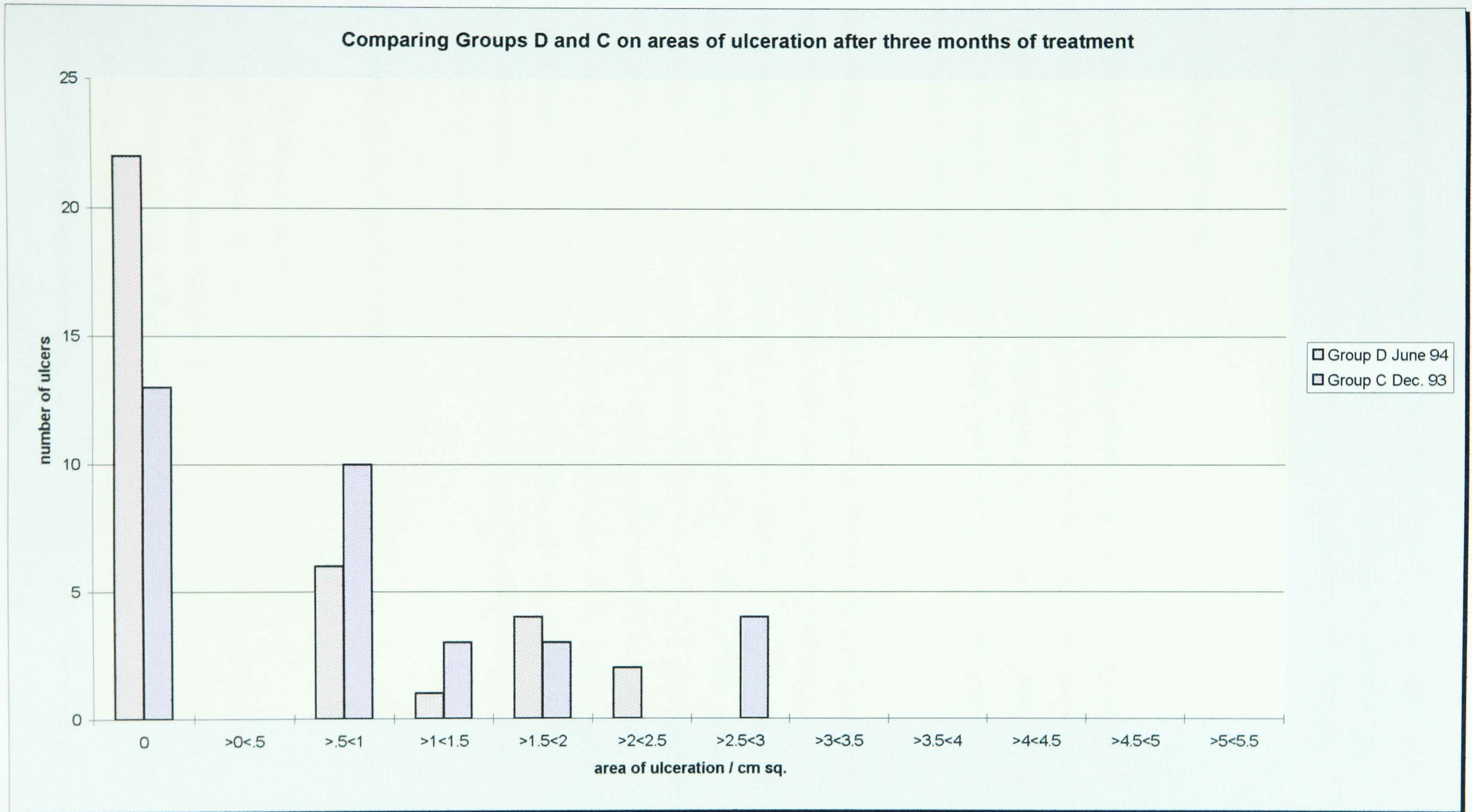
n = 34 mean ulcer area = 5.2cm² S.D.= 9.1 Median = 0 cm²

U = 715 U' = 407

Two Tailed P = 0.07

95% C.I. = 0 to 0.78

Figure 29



Having matched the groups on ulcer area it was found that after three month periods 39.4% of Group C were healed whilst 62.8% of group D ulcers were healed. The two tailed value indicates that the findings, relating to Group D in June 1994 and Group C in December 1993, approached significance.

4.3.4 SUMMARY OF RESULTS

Based on the results of the March 1994 assessment it was found that subjects in the Experimental group were more likely to present with healed ulcers than subjects in the Control group. In response to this finding subjects in the control group were also supplied with orthoses. An advantage of this development was that the suggested efficacy could be further challenged.

Subjects continuing in the trial from its onset until September 1994 were considered in this aspect of the study. Subjects who had constituted the Experimental and Control groups were reallocated to groups C and D respectively. When compared on ulcer area in March these groups were significantly different. Whereas 58% of ulcer sites in Group C were healed only 14% of ulcer sites in Group D were healed. In June 1994, 3 months after Group D were supplied with orthoses, 62% of ulcer sites in group D had healed and 60 % of sites in group C had healed. These results suggest that orthoses, supplied by persons other than the author, were also effective. This finding demonstrates that the effects appear to be repeatable, thereby strengthening the validity of intervention efficacy.

4.4 ASSESSMENT OF IMPLEMENTATION

Based on the results it could be inferred that the orthoses supplied by the physiotherapy department were associated with higher than expected numbers of healed ulcers. This may be an indication that the method of prescription and supply was successfully implemented. The author chose to test the assumption further. It was hypothesised that orthoses supplied by him would be more effective than those supplied by the physiotherapy department. To test the hypothesis the author sought to

match the groups on ulcer area and examine the effects after similar periods of time. It was decided that findings relating to Group C from September 1993 to December 1993 could be compared with findings relating to Group D from March 1994 to June 1994. Thus both groups could be compared on ulcer area for a similar duration of treatment. Limitations to this approach are discussed below.

By September 1993 Group C had been wearing orthoses for periods of between 4 to 6 weeks whereas Group D was supplied with new footwear and orthoses in March 1994. Although the groups could be matched for ulcer area, observations are subject to the limitations of time related factors (e.g., wear and tear on orthoses / footwear and subject diligence). These variables may have biased findings in favour of Group D. The validity of conclusions drawn is also subject to potentially different seasonal and consequential social differences between groups. Seasonal differences between these periods are not extreme, although the period from March to June (pre Monsoon) is hotter than the post Monsoon period between September and December.

Group D and Group C were compared on the same variable (area of ulceration) after a similar time lapse i.e. after three month periods. Group C data collected at the December 1993 assessment was compared with Group D data collected at the June 1994 assessment. The findings demonstrate that, given similar dimensions, ulcers responded to treatment, over time, in a similar fashion. A one tailed probability value ($P=0.03$) suggested that the improvement in ulcer dimensions in Group D was significantly better than improvements in Group C. An explanation for this finding may be that whereas Group D had been supplied with new sandals at the beginning of their period of interest, Group C had been wearing sandals for between 4 to 6 weeks prior to their period of interest.

It is possible that the results may have been biased by more diligent follow up care of the subjects in Group D (the author was absent from the hospital in the interim period). However this suggestion does not deflect from the conclusion that the technician (under the authority of the physiotherapist) was capable of prescribing and

supplying orthoses that were efficacious. It should also be considered that the orthoses prescribed and supplied by the physiotherapy department may have been more effective than those supplied by the author.

Considering the findings, a null hypothesis of no difference between the physiotherapy department and the author (when compared on the effects of orthotic intervention) cannot be rejected. It would appear therefore that the method of prescription and supply was successfully implemented.

4.5 The Sustainability Of The Service

Aims:

The establishment of an infrastructure to sustain a podiatric service has been described and the ability of the physiotherapy department to prescribe and supply orthoses successfully has been demonstrated. However, the service has not been sustained. Although some patients are supplied with orthoses, the service is conducted on an ad hoc basis with no clear strategy to integrate the approach into a structured impairment control programme. The aim of this aspect of the study is to present an analysis of the causes and effects of service breakdown.

4.5.1 BACKGROUND

The remit of the physiotherapy technician includes all outpatient ulcer treatment and follow up at Dr Bandorawalla Leprosy Hospital. As many as sixty patients may be seen during the clinic which is held every Saturday afternoon. Apart from the assistance of "dressers" the physiotherapy technician conducts these clinics single handed. He is responsible for referring patients with acute infection or patients requiring surgical intervention to a physician or the orthopaedic surgeon. Apart from the subjects included in this study no records are maintained for patients who present for treatment but are not referred to senior medical personnel.

It was during these clinics and at informal opportunistic occasions that the physiotherapy technician would ascertain the condition of orthoses. In this manner the majority of subjects would be contacted frequently. A more concerted effort was made to contact other subjects who were more self reliant, or less diligent and were consequently seen less frequently at the hospital. A more comprehensive examination was conducted during the formal assessment periods. Formal and informal observations made by the physiotherapy technician were reported to the physiotherapist who recorded relevant information. Until December 1994 such records had been satisfactorily maintained and individual histories yielded sufficient

information to identify general issues relating to the treatment.

During the month of December 1994, the physiotherapy technician underwent a domestic crisis. During this period he was unable to function adequately and only conducted essential ulcer follow up procedures. A further consequence was that interest in the trial was abandoned. Out of respect and regret for his situation, subjects who would otherwise have reported to him with damaged orthoses or sandals refrained from so doing. Other subjects, who may have developed problems that would have been identified during routine examinations were neglected.

Although a prosthetics technician had also received training, the physiotherapist lacked confidence in his motivation and reliability and was unwilling to recruit him to pursue the task formerly undertaken by the physiotherapy technician. On my arrival in January 1995 a rapid assessment of the situation was that the project had effectively been abandoned. A further issue, related to those already alluded to, dictated that there was little possibility of reviving the project protocol. The physiotherapy technician had also entered into negotiations with an alternative leprosy control organisation and was anticipating moving to a north eastern district of India. It was apparent that there was no suitable replacement for him.

Consequent developments

The situation in January, however, presented a further opportunity that had not been anticipated. All the subjects that had presented at the September 1994 assessment were available for ulcer assessment in January 1995. Data relating to subjects still wearing orthoses could be compared with subjects no longer wearing orthoses. Analysis of this data could be used to test a null hypothesis that indications of recurrence or regression of ulceration were not associated with an abandonment of orthoses. Inferences drawn from these findings would be augmented by assessment data collected after a one year period. A return visit was planned for November / December 1995 to facilitate data collection. Invitations to present for assessment during this period would be extended to all subjects. Ulcer assessments would be conducted and a final review of any remaining orthoses would be conducted.

Comparisons would then be drawn between subjects that had been without orthoses for variable periods of time and subjects still wearing orthoses.

By February the physiotherapy technician had returned to full time employment. He was willing to assist by attending to any subject who requested attention but was unwilling to conduct more detailed follow up. Furthermore he refused to pursue determined defaulters. This service he would continue until his departure in July when he planned to assume his new position. By September 1995 it was apparent that he had decided not to leave Dr Bandorawalla Leprosy Hospital to pursue the appointment offered to him. He therefore continued to offer the reduced service until the author's visit in November 1995.

4.5.2 METHOD

By January 1995, 17 subjects were no longer wearing orthoses. Of this number, 10 reported that they had been without orthoses for periods of between 4 to 6 weeks. The remaining 7 subjects declared that they had been without orthoses for between 2 to 4 weeks.

Forty subjects presenting for assessment in January 1995 were still wearing orthoses. Subjects still wearing orthoses were designated to **Group 1**. Subjects no longer wearing orthoses were designated to **Group 2**.

Table 26: Sample Details, January 1995 Assessment

Group	Individuals			Feet	Sites of interest*
	Mean Age	Male	Female		
1	46.7 (SD 12.2)	28	12	42	50
2	33.7 (S.D8.3)	17	0	20	20

The scenario in December 1995

After a period of 11 months all subjects, who had responded to invitations to present for assessment in January 1995, were requested to present for assessment in December 1995. All subjects presented for assessment.

By December, 32 subjects were no longer wearing orthoses, whilst the remaining 23 subjects had continued to wear their orthoses. None of the subjects who presented without orthoses in January had sought replacement devices. Of those subjects continuing to wear orthoses, the majority had reported to the physiotherapy technician when changing footwear or when they considered that their orthoses needed replacement or repair. Some subjects volunteered the information that they had taken the responsibility of reapplying their orthoses themselves.

Subjects still wearing orthoses in December 1995 were designated to **Group 1+**. Subjects no longer wearing orthoses were designated to **Group 2 -**. **Group 2 -** included all those subjects who had been allocated to **Group 2** following the January assessment.

Table 27: Sample Details, December 1995 Assessment

Group	Individuals			Feet	Sites of interest*
	Mean Age	Male	Female		
1 +	40.6 (SD 12.2)	15	10	25	29
2 -	39.8 (S.D10.3)	30	2	37	41

4.5.2.1 Data Collected in January 1995

Ulcer status at sites of interest was categorised as **Healed**, **Resolving** or **Regressing**. **Resolving** denotes ulcers that had an area that was less than that recorded at the September assessment. **Regressing** denotes ulcers that had an increased area or an area that had not altered since the September assessment. Sites that had been healed at the September assessment, but where a recurrence of ulceration was presented, were also categorised as **Regressing**. Where no change in dimension was recorded for an active ulcer the site was categorised as **Regressing**.

χ^2 test was used to test the null hypothesis that subjects in **Group2** were not different from subjects in **Group 1** when compared on ulcer status. (Ulcers categorised as **Resolving** were excluded to facilitate χ^2 test.)

The Fisher-Irwin exact Test was used to test the null hypothesis that subjects in **Group 2**, who had been without orthoses for more than 4 weeks, were different from subjects in the same group who had been without orthoses for less than 4 weeks.

4.5.2.2 Data Collected in December 1995

Ulcer status at sites of interest were categorised as **Healed**, **Resolving** or **Regressing**. **Resolving** denotes ulcers that had an area that was less than that recorded at the January assessment. **Regressing** denotes ulcers that had an increased area or an area that had not altered since the January assessment. Sites that had been healed at the January assessment, but where a recurrence of ulceration was presented, were also categorised as **Regressing**. Where no change in dimension was recorded for an active ulcer the site was categorised as **Regressing**.

χ^2 test was used to test the null hypothesis that subjects in **Group2-** were not different from subjects in **Group 1+** when compared on ulcer status. (Ulcers categorised as **Resolving** were grouped with ulcers categorised as **Regressing** to facilitate χ^2 test.)

4.5.3 RESULTS

Table 28: **Comparison of Ulcer Status Between Group 1 and Group 2 Following Assessment in January 1995.**

	Healed	Resolving	Regressing	Total
Group 1	34	4	12	50
Group 2	11	1	8	20
Total	45	5	20	70

$\chi^2 = 1.61$ 2df 95% confidence P = 0.20

Table 29:
Comparison of Ulcer Status in Group 2 Following Assessment in January 1995

	Healed	Resolving	Regressing	Total
> 4 weeks	5	1	7	13
< 4 weeks	6	0	1	7
Total	11	1	8	20

$\chi^2 = 3.5.$ 2df 95% confidence P = 0.06

Table 30: **Comparison of ulcer status between Group 1+ and Group 2 - following assessment in December 1995.**

	Healed	Resolving	Regressing	Total
Group 1 +	23	4	2	29
Group 2 -	23	5	13	41
Total	46	9	15	70

$\chi^2 = 4.06$ 2df 95% confidence P = 0.04

The results demonstrate that over a short period of time those who continued to wear orthoses did not appear to be advantaged when compared with those who had abandoned their orthoses. The sample that had abandoned their orthoses was small, significance was therefore difficult to demonstrate. Within Group 2 it was demonstrated that the difference between subjects that had been without orthoses for more than month and those who had been without them for less than one month approached significance.

After a period of eleven months it was demonstrated that there was a significant difference between the two groups; i.e. that there were a greater number of regressions and recurrences amongst the group who had abandoned their orthoses.

Of those subjects found to have abandoned their orthoses between September 1994 and January 1995, 3 had presented with healed ulcers at the September assessment (i.e. there had been a recurrence of ulceration by January). However, there had also been a recurrence of 3 ulcers in the group that had continued to wear their orthoses. The 3 subjects who had continued to wear orthoses, but presented with a recurrence of ulceration, all presented with badly misshapen footwear and, consequently,

incompetent orthoses in January. The 3 subjects who had abandoned their orthoses did so when new footwear had been issued to them. As their ulcers had healed they did not perceive a necessity to continue wearing orthoses.

It was noteworthy that of the sites that had a recurrence of ulceration, none had been healed for more than six months. There was no recurrence of ulceration at sites that had been healed for periods greater than six months. This observation applied to subjects from either group. This observation relates to a small sample and may be idiosyncratic. It may indicate, however, that a sustained period of healing does allow for the development of greater integrity of the integument. This theory was discussed earlier (section 2.4.3.). It may also be that a sustained period of appropriate orthotic intervention encourages soft tissue adaptations (after Davis' law) that enhance pedal mechanics. It is with temerity that such a hypothesis is suggested. If such an association could be demonstrated it would follow that after a period of time, similar to that over which orthotic intervention was applied, the foot would again adapt in response to predisposing factors that disadvantaged it formerly.

It was widely assumed by the subjects that, although the orthoses were of value, once the ulcers had healed there was no further necessity to continue wearing them (see Chapter 5). For a majority of subjects who did abandon their orthoses, after their ulcers had healed, this opinion appears to have support. Of the 25 sites that were healed in January 1995 there was a recurrence at 4 sites by December 1995. Including the 3 subjects who had abandoned their orthoses in November/December 1994, there were 7 sites presenting with ulceration in December 1995, following the abandonment of orthoses. Considering the sites of interest of those who abandoned their orthoses (Group 2-) before their ulcers had healed ($n = 13$ including the 3 recurrences recorded in January), all but 4 sites demonstrated a regression since January 1995.

2 of the subjects that had been wearing orthoses in January (Group 1) but presented with a recurrence of ulceration, continued to wear orthoses fitted into new sandals. These subjects both presented with healed ulcers in December. The third subject from Group 1, who had presented with recurrence, accepted new sandals with a

replacement orthosis. However, at some stage during 1995 she abandoned the orthosis to satisfy her need for less stigmatising footwear. She reported that her ulcer had healed before she changed her footwear (and consequently abandoned her orthosis) but when she presented for assessment in December there was a recurrence of ulceration at the site of interest.

Amongst the group that had worn orthoses continuously until December 1995 (Group 1+) there had been no recurrence of ulceration (at the December assessment). Furthermore only one ulcer demonstrated regression, a second ulcer had been recorded as presenting with an area unchanged from the January assessment. Four other ulcers continued to demonstrate a gradual resolution.

In summary, the salient features of the results are as follows:

1. At the January 1995 assessment, there was no significant difference between subjects found to be wearing orthoses and those who were not. These groups were compared on the status of sites of interest. Subjects found not to be wearing orthoses reported that they had abandoned their devices for periods varying from approximately 6 weeks to 2 weeks.
2. The difference between subjects who were without orthoses for more than 1 month and subjects who were without orthoses for less than one month approached significance.
3. After a period of 11 months there was a significant difference between subjects who had continued to wear orthoses and those who did not, when compared on the status of sites of interest on the plantar aspect of the foot. Subjects who had continued to wear their orthoses did not present with recurrence or regression of ulceration (in all but 1 case).

4.6 DISCUSSION

Some evidence has been presented to support the suggestion that the continued application of orthotic therapy may have a role in the prevention of ulcer recurrence. The evidence is not as compelling as the results that demonstrated the more immediate therapeutic benefits, or the results that suggest the role of orthoses in inhibiting the regression of ulceration. It may be that, for some, variables yet unidentified will confound attempts to heal ulcers using orthotic intervention. It is clear, however, that even for subjects such as these, continued orthotic intervention can be of benefit. Clearly controlling the area of ulceration exposed to infection should not be considered insignificant.

It is the author's contention that had a systematic approach, including enthusiastic and diligent follow up procedures, been sustained, the results of this trial would have been even more decisive. The focus for further discussion therefore centres not on efficacy but on the issue of sustainability.

Bossert (1990) published the findings of a comparative study of health projects in Central America and Africa. These were, in the main large projects sponsored by the U. S. Agency for International Development (A.I.D.). He identified key context factors and project characteristics related to project sustainability. The "sustainability factors" referred to in his study are based on previous studies and co-workers' observations and may consequently be flawed by subjective interpretation. The validity of his model, however, is supported by similar observations from other investigators and commentators (Miles 1989, Maclachlan 1993, Price 1994). Being, in the main, relevant to large donor funded projects some of the factors identified are inappropriate for discussion here. There are, nevertheless, some general criteria that are applicable in the context of this study and these factors will be considered in the development of this discussion.

4.6.1 Context factors

The sustainability of programmes that are implemented are dependent, in part, on context factors. These criteria are thought to be generally beyond the control of project designers but must be considered in the planning process if sustainability is a desired goal. As declared earlier, not all the context factors listed by Bossert are considered relevant here, however there are two which are considered salient. One major factor is the influence of socio-cultural factors and the other is the role of the implementing institution.

4.6.1.1 Socio-cultural Factors

"A country's inherited culture is not a fragile historic artefact but a dynamic current synthesis of differing influences over the ages." (MacLachlan 1993)

In striving to be culturally sensitive and avoiding Eurocentric prejudice, there is a danger of failing to identify what Miles (1989) termed "the concept gap" which exists between the West and the Indian sub continent. Narasimhan and Mukherjee are considered by Miles to be senior Asian rehabilitation policy makers. Miles cites their opinion that, *"there is a close parallel between the disability situation in India, and in other developing countries today, and the situation in developed countries a few decades ago."* The difficulty for Indian policy makers lies in finding western developments that are relevant to their situation. This dilemma was verbalised by Kenkre (1993) when she appealed for a pragmatic approach in the development of assistive devices for the disabled in the Indian sub-continent. There is no value judgement associated with accepting that there is a concept gap and indeed failure to do so may only result in attempts to implement inappropriate and consequently unsustainable innovations.

Pragmatism was considered a fundamental concept in the design of the project. Only available resources and facilities were used to ensure continuity. By so doing it is considered that, in this respect, socio-cultural sensitivity was observed. However

socio-cultural sensitivity extends beyond material and technical considerations. The intricacies and subtleties of Indian social protocol are based on a deeply inculcated cultural inheritance. A partial failure to recognise the significance of such influences and to respond appropriately may have jeopardised the sustainability of the project. These factors are interrelated with the second of Bossert's "Contextual Factors" which are considered to be relevant to this discussion. Bossert identified "The Implementing Institution" as a contextual factor to be taken into account. Whilst discussing this factor, the sociocultural elements, alluded to above, will be developed.

4.6.1.2 The Implementing Institution

Much of Maclachlan's criticism of the development of rehabilitation programmes in Pakistan is compatible with Bossert's observations relating to the role of the implementing institution. It has been reported that, where institutions were debilitated by *"competing objectives, poor leadership, low skill levels and unresponsive bureaucratic centralisation"* (Bossert 1990 p 1018), it was unlikely that projects would be sustained. Well-integrated institutions, with goal structures consistent with the project goals, were an advantage, particularly where there was less likelihood of fragmentation due to poor leadership.

At the time of composing this thesis, it is widely agreed that the level of skills available at Dr Bandorawalla Leprosy Hospital are exceptional. However, highly qualified and well-motivated personnel have become discouraged and apathetic largely because of the negative factors discussed above. It is the opinion of senior medical personnel that The Poona District Leprosy Committee (P.D.L.C.) has diverted its primary focus of attention away from its former emphasis on disability prevention and impairment control. The social and economic rehabilitation of the disabled is currently favoured as their primary concern. Whether this perspective is correct is perhaps not the most important issue, for it remains that this is at least how the situation is perceived. It is perceived that the highly centralised and autocratic leadership from the P.D.L.C. has not responded to address the issue. The pervading perception is that the executive body is uninterested and distant (both physically and

emotionally) where the concerns of the hospital are regarded. Morale continues to fall and there is a general dissipation of enthusiasm and motivation throughout the hospital.

Even though an excellent rapport developed between the Hospital staff and the author, until the latter stages of the project, it was difficult to enthuse the senior medical personnel to an extent where they might actively pursue more than a superficial interest in the project. This was primarily because they felt powerless to act on the author's recommendations. This apathy extended as far as (but did not include) the physiotherapy technician. He conducted his obligations diligently until his personal crisis. Had the hospital administration been more actively involved in overseeing the project and responding to suggestions made, suitable contingency plans might have been activated and continuity maintained. Following the assessment in March 1994 objective evidence was available to support the efficacy of the treatment. It was suggested then that a suitable candidate should be sought and trained as a "podiatry technician". In the author's opinion, the physiotherapy technician's efforts were commendable. However, his remit was extensive and could not realistically include the service the author felt should be provided if the wider population was to be served. The author's suggestion was accepted as valid, but was rejected by senior medical personnel as it was felt that such a recommendation would not be countenanced by the P.D.L.C.

4.6.1.3 Nuances In Social Interaction

There may be a further dimension complicating the issues identified above. This concerns subtleties of Indian social protocol alluded to earlier. The courtesy extended to visitors is an obligation (perceived by many as a privileged opportunity) based on Hindu ideology but extended to be a cultural rather than a sectarian phenomenon. There is an indulgence extended toward Western visitors who are not generally familiar with cultural norms. However, had the author demonstrated a greater awareness of social protocol and cultural conventions stronger support from the more influential sectors associated with the project may have been procured.

Focused primarily on the immediate practicalities of the project, the most intense interaction the author experienced was with the physiotherapy technician and with the subjects of the trial. Inevitably a close professional and personal relationship developed between the author and the technician. As the study developed and it became necessary for him to develop his insight of the social system at Kondhawa the author also developed relationships with many leprosy impaired individuals and families. The effects of these relationships may have influenced the outcome of the study.

Assuming Goffman's theory (see section 5.3.6.7), it is probable that the author had become a "courtesy member" of Kondhawa's leprosy impaired population. As such he may have been socially distanced from those more able to influence policy decisions. Interaction between social groups and the eradication of caste discrimination was a Gandhian objective supported by legislation. Laudable though such Gandhian principles are, the reality is that Hindu philosophy has profoundly influenced Indian perspectives and values (see 5.1). True pragmatism demands that social distances between groups should at least be acknowledged. Wealth and academic or professional prestige may advance the privilege of choosing social group affiliation. It would be well to consider the social restraints and sanctions associated with such a choice. It might have been expedient for the author to have maintained greater distance from the population and fostered a closer professional relationship with those in positions of greater authority. It could be conjectured that had the author done so the project might have been more successfully sustained and the population would have been better served. However, it is the author's opinion that the fragmenting administrative infrastructure was a more significant factor.

4.6.2 PROJECT CHARACTERISTICS

Further sustainability factors identified by Bossert were listed as "*project characteristics*". Unlike the "context factors" discussed above it is suggested that this group of variables is affected by the decisions and actions of project designers and implementors. Bossert composed a comprehensive list of factors. Some of the factors

listed are clearly relevant when considering the input of major fund donors, however such factors need not be considered in this discussion. Features that are pertinent to this discussion include:

- Project integration
- Mutually respectful negotiating process
- Training
- Perceived project effectiveness
- Community participation

4.6.2.1 Project integration

It was not intended to conduct the project as a vertically run separate hierarchy within the institution. An objective was to implement an integrated programme into an existing institutional hierarchy where many institutional actors could be involved. In so doing it was reasoned that those involved would develop interests dependent on the continuation of the project. Considering Bossert's finding this rationale was sound. Health projects run in Central America and Africa were found not to have been sustainable where vertical programmes were implicated in the development of *"institutional jealousies and turf fighting"*.

Although the project did not generate as much interest and involvement as was hoped (partly due to the contextual factors discussed above) it appears not to have been considered by other departments as exclusive. Where friction did develop it was related to the role and status of the physiotherapy technician. The footwear department resented the assumed authority of the physiotherapy technician and only grudgingly co-operated with his requests. This issue might have been resolved through diplomatic personnel management but there was no structure for this purpose. During visits, to the hospital the author's requests were given immediate attention and at no time was co-operation denied. However, in his absence, hostility toward the physiotherapy technician resumed.

The problem outlined above was a significant factor affecting the sustainability of the

project where the dependency on promptly supplied, well-fitted footwear was fundamental. The technician was wary of resentment and subjects grew dissatisfied with the grudging service.

4.6.2.2 Mutually respectful negotiating process

Projects approved in a mutually respectful negotiating process are more likely to be sustained than projects that are viewed as an imposition. The A.I.D. experience demonstrated that where officials felt that they had been excluded from negotiations, the same officials became the major opponents of the project (Bossert 1990). This principle accounts for some of the issues associated with this project.

In the early stages of the project the author had been advised that as the principal investigator he should negotiate only with Dr J. Mehta with whom administrative authority rests. As explained earlier, leadership from The P.D.L.C. is highly centralised and autocratic. It had been expected that all relevant information would be communicated to senior staff at Dr Bandorawalla Leprosy Hospital through the P.D.L.C. However, during a routine visit it was brought to the author's attention that information had not been filtered to Dr Bandorawalla Leprosy Hospital. Senior staff had felt excluded and resented the apparent disregard for their status and sensibilities. At this stage it was recorded that there was discernible opposition to the project. The Physiotherapy technician also reported that he had experienced some opposition to his attempts to carry out project obligations. Dialogue was established and the issue was discussed. In response to their criticism the author made a commitment to ensure that each member concerned would be kept informed of all developments, personally. This development initiated an acceleration in interest and co-operation.

4.6.2.3 Training

Price's analysis of issues related to the sustainability of early intervention programmes in the South Pacific highlights a problem common with other developing countries (Price 1994). She suggested that resources are not available to train large numbers of

professionals to serve relatively low-status minority groups, and advocates the transmittal of services from health professionals to middle level health workers. In this way the multifarious skills of one highly trained professional can be disseminated, through training, to groups of field workers. This policy is sound not only because it is pragmatic but because it has been demonstrated that projects with a strong training component tend to be sustained where those without training do not. Bossert found that where facilities and inducements for trainees to use acquired skills had been implemented, there was a stronger probability that activities would be sustained. Training programmes that raised individuals' potential for procuring further employment are particularly esteemed. Training should, therefore, be considered an investment as it produces valuable human resources. Training was a major objective of this project. Evidence to support the suggestion that the objective was met has been presented.

This aspect of the project has raised considerable interest and has been a focus for discussion at ILEP meetings. An introductory programme entitled "A workshop on the podiatric management of the neuropathic foot" was conducted at the Byramjee Jeejeebhoy Medical College in Pune. This workshop developed because of a perceived demand for information. It was hosted by the P.D.L.C. and was conducted by a faculty including personnel from the United Kingdom and India. It was attended by fifty delegates, the majority of whom were from India (3 attended from Nepal and 1 from China). A proposal to conduct training programmes for technicians has been requested jointly by Lepra India and The Leprosy Mission, India. Further requests to conduct similar programmes in other centres in South East Asia and China are also being considered.

These developments reflect a further point made by Bossert in his observations relating to the effectiveness of training. He noted that where training had been successfully implemented, *"the trainers themselves tend also to continue to train other human resources."*

4.6.2.4 Perceived project effectiveness

Projects with a reputation for achieving defined goals and objectives with a relatively efficient use of resources are likely to be sustained. Interestingly it appears that it is not objective evidence (in the A.I.D. context this related to cost effectiveness analyses) that affects sustainability but the reputation for effectiveness. Effectiveness was based on some form of indicator that projects were achieving desired goals. An example is cited of maternal and child health centres in Zaire. It was reasoned that these were well sustained because they could demonstrate that they had reduced demands on maternity wards. They had also provided immunisations and health education to the population and presented maternal and child health training to nurses (Bossert 1990).

A publication (Cross 1995) and "A Workshop On The Podiatric Management Of The Neuropathic Foot" contributed to a developing international interest in the project at Kondhawa. It is suggested that these factors helped to precipitate a request, by Dr Mehta, to institute a "podiatry technician" at Dr Bandorawalla Leprosy Hospital. As suggested earlier, had such a resource been implemented earlier in the project the service might have been sustained more effectively throughout 1995.

4.6.2.5 Community participation

Bossert (1990) hypothesised that sustainability would be enhanced by encouraging community participation. His rationale was that by so doing a constituency would be created that would demand continuation of the project activities. However although he found that projects which had community participation attracted beneficiaries there was no relationship between sustainability and community participation per se. The voice of the recipients of services was found not to be significant factor. Similarly the demand for a continuation of the service by subjects in the trial, and by others who had observed beneficial effects, had little effect. An explanation for this is that the infrastructure to provide a consistent and dependable service was inadequate.

CHAPTER 5

THE ATTITUDES OF SUBJECTS TO ORTHOTIC TREATMENT: A CRITERION FOR ACCEPTABILITY

AIMS:

In this study, acceptability is a parameter indicated by attitudinal variables. This aspect of the investigation aims to demonstrate whether attitudes toward the intervention were consistently positive. If so it may be inferred that orthotic intervention is an acceptable form of approach for the study population.

This chapter will address the following:

1. The social and cultural context in which the study was undertaken.
2. The methods of schedule design and implementation.
3. Results and analysis of schedule data.
4. The acceptability of the intervention, as inferred from the results.

5.1 INTRODUCTION

5.1.1 THE MEANING OF LEPROSY

It was Waxler's contention that the tragedy of leprosy has little to do with the bacillus (1981). In her perspective the patient's experience of the disease is profoundly affected by the social beliefs and expectations of the society in which the individual is a part. Valencia (1989) warns that conventional models should not be used to evaluate the affects of leprosy. She argues that it is not simply a dysfunction of physiological disorder but it has manifestations that profoundly affect the patient's family and community. The psycho-social dysfunction implied is a complex issue. The leprosy impaired are not simply labelled as deviant by external agents. In the literature, there appears to be a consensus on this issue. It is suggested that the patient him/herself is one, amongst other interacting agents, that contributes to the development and perpetuation of a self image within his/her social environment. It is, however, in the course of social interaction that values and rules are constructed.

There are pre-existing cultural systems of ideas that are used, within the context of social interaction, to create and evaluate the labels that direct societal behaviour (Waxler 1981, Berreman 1984, Rao 1992). Given the profound effect of classical Hindu philosophy on Indian society the term "*Illness of Untouchability*" (Berreman 1984) is an apt description of Indian leprosy. Its connotations of "sub-caste", ritual pollution and mystical agents of social control reflect the social and cultural context of the disease in which the meaning of leprosy has developed and is perpetuated. These issues are salient features of the contextual validity of the interview findings and will be presented to provide a relevant frame of reference.

5.1.2. The illness of untouchability: Hansen's disease or leprosy?

Before continuing to examine the implications of the disease there is a fundamental point to be established. This may be conveyed by the words of Rao (1992) who stated that, "*The general perception of leprosy within a community is confined to conditions associated with deformity*". This observation is repeated with emphasis throughout the literature. Any discussion on leprosy is essentially a discussion on the meaning of the deformities associated with the disease and not the disease per se. Rao demonstrated that 81% of respondents in his survey¹⁵ did not recognise that hypo pigmented patches or nodules were a symptom of leprosy. However, 89.6% of the same group associated leprosy with deformity or ulceration. These data suggest profound significance in understanding the perception of the disease by the communities and the effect of community response toward the sufferer. Of the 590 patients Rao studied 464 (78.6%) had no deformity. Of this sample 93.3% stated that they were not isolated by their communities. Of the 126 patients with deformity however, 113 (89.1%) were isolated by their communities.

To the majority, leprosy means deformity which is a physical and psycho-social abomination. The WHO stated an objective of eradicating Hansen's disease by the

15. Rao carried out a survey on a 20% systematic random sample of the households in the Chingleput district of Tamil Nadu. 281 households were interviewed 90.8% were Hindus, 6.4% were Christians and 2.9% were Muslims (Rao 1992 page 331.)

year 2000. Unlikely though this may appear, the activity of the bacillus may be sufficiently curtailed so that it no longer presents a threat as a public health problem. It is my contention, however, that as long as deformity persists "leprosy" too will persist. If a greater emphasis is laid on disability prevention and impairment control, the eradication of leprosy may truly be achieved.

In India leprosy is primarily a social catastrophe, the bacillus is not virulent and deaths are not attributed to leprosy infection *per se*. There is an increased morbidity due to chronic neurological, dermatological and muscular impairment that contributes to an erosion of the quality of life. The WHO (1988a) has verified that death rates are higher among leprosy sufferers than among others in any given population. The psychological effects of chronic morbidity are also affected by sociocultural variables. Lal (1974) considered the institutionalisation of leprosy patients seeking treatment for ulceration. She identified mental attitudes of dependence that developed amongst those needing long term care. Reviewing the need for psychiatric care of leprosy patients in India Weis *et al.* (1992) cite Behere as reporting suicidal ideation in 14 of 24 randomly selected leprosy inpatients in Banares. These findings are not surprising given the powerful Hindu identity that pervades Indian life.

The development of any therapeutic approach to disability prevention in leprosy should not be based on a medical model. The distress related to the disease is relative to the social suffering it causes, more so than the distress being an expression of physical suffering. The effectiveness of a therapy, therefore, should be determined by its effects on the ability of the patient to pursue the goals established by his/her culture.

5.1.3 THE MEANING OF THE DISEASE FOR THE INDIVIDUAL

Regional variations in social structure inevitably influence the experience of individuals as emphases and priorities change. However from the studies of Rao (1992) and Berreman (1984) a general explanation for the cause of disease is that it is a manifestation of spiritual displeasure or *Karma*. This was the most commonly

expressed view in Rao's study where 31.3% communicated this view. 16.7% suggested that the disease was a manifestation of socially unacceptable behaviour (primarily sexual) (Rao 1992 p.342). Social norms are, however, predominantly a reflection of Hindu teaching (discussed later). The religious association with the disease therefore, does appear to be fundamental. The implications of this opinion for self esteem and motivation to seek cure may be significant.

An interesting case study is that of the Dharwar district of Karnataka (Berreman 1984) where leprosy is considered to be the result of a curse by a local deity. Again, the term "leprosy" is reserved mainly for those with characteristic deformity or ulceration. Paradoxically, *Yellama*, the local goddess considered to be responsible for "leprosy" is also thought to be responsible for *kali* or *tadu* which are local terms relating to the anaesthetic patch of early leprosy. These are not locally accepted as being associated with leprosy. The common local term for these patches is *Yellama Huu* (Flowers of Yellama). It is suggested that the symptom may have been ascribed this favourable term in order that the goddess should not be further offended. Offence may provoke her to wrath expressed in the curse *heri bene* (the "big disease", i.e. leprosy). The indication is, therefore, that there is a subconscious association between the two manifestations separated by a fearful unwillingness to acknowledge the relationship. The implication is that regression of the patient into more serious disease, resulting in deformity, is a manifestation of a lack of moral or spiritual fibre.

A practicable effect on the ritual status of the individual is suggested by Rao (1992). He recorded that although 69% of patients were able to worship with others 27.4% observed a constraint to worship in isolation. Rao did not indicate if deformity dictated whether patients were excluded either through covert or overt censure. Rao and Berreman (1984) both made an interesting observation. They recorded that although the disease was widely thought to have a spiritual cause, very few considered "spiritual" healing to be a valid approach to treatment. The role of causal and recovery beliefs is discussed later.

Discrimination against the leprosy deformed is not restricted to those who do not

suffer the disease. Of 345 patients to whom drugs were to be dispensed 52.8% confirmed that they were reluctant to stand alongside deformed patients. A majority of this number indicated that their hesitancy was due to an unwillingness to be associated with leprosy amongst other villagers. A considerable number however expressed disquiet caused primarily by the proximity of the deformed (Rao 1992).

Perhaps one of the strongest indications of the "subcaste" development is the pattern of marital relationships. During periodic visits to Kondhawa I observed an interesting marital phenomenon. The marriage of a leprosy impaired patient was restricted either to one similarly afflicted or to an unaffected child from a family in which one or both parents were afflicted. It is not expected that an unaffected child of leprosy parents could be married into a family with no history of leprosy. This constrained intermarriage is characteristic of traditional caste observance and as such provides an identity of "untouchability". The observation is validated by Rao's findings in Tamil Nadu where data indicated the unwillingness of unaffected families to accept the children of leprosy patients as spouses for their offspring (Rao 1992).

The proposed concept of "subcaste" is further strengthened by socioeconomic restrictions whereby patients are discriminated against in attempts to secure employment or housing. Trading enterprises run by leprosy individuals were boycotted by 82% of respondents in Rao's study and fewer than 28% of employers would consider employing subjects displaying indications of leprosy. Of those who indicated an acceptance of leprosy employees, the work that might be offered was primarily agricultural or other manual labour (again, traditionally the reserve of the lower castes). It is emphasised throughout the studies of Rao and Berreman that "leprosy" is generally accepted by the unaffected as applying only to the deformed or ulcerated. The label persists regardless of the bacteriological status of the individual. Consequently many cured or "burnt out" cases who pose no threat whatsoever are discriminated against. Ironically other individuals with established multibacillary disease, who may not have developed characteristic deformity but present a high risk of contamination, move more freely in their communities.

5.1.4 THE "LEPER"

Clearly the chronic nature of the disease with its potential to inflict gross deformity is traumatic primarily for the patient, but also for his social environment. From the initial negative response of others through the exasperating years in which the patient dutifully accepts his new role as "leper", the beliefs and myths surrounding the disease develop.

A dominant feature of the Indian Government's leprosy eradication strategy is education. Clearly, secularisation and the further integration of the disease into mainstream health care, inter-related with health education, should contribute to the gradual demythification of leprosy. Perhaps what is even more important is that models for community based rehabilitation should be identified and replicated to assist in the enhancement of the social and economic status of the leprosy disabled (Mehta *et al.* 1992) .

The relevance of these issues is realised when the broader context of Indian Society and culture are considered. For this purpose an impressionistic profile is presented below.

5.1.5 INDIA: A PARADOX OF ANTIQUITY IN MODERNITY

As India strives toward modernisation, the four dimensions interactive in Indian society-family relationships (ecological, economic, political and system of values) are undergoing change in emphasis. Trends toward industrialisation and urbanisation have disturbed the social equilibrium causing the balance to shift away from characteristic traditional Indian Society (Liddle and Joshi 1986, Ghadially 1988, Littlewood and Lipsedge 1989). However, it appears that, although traditional structural norms and values are continually modified, they are not abandoned. Indeed, the system of values, embodied in emergent economic and political institutions, appear less influential on Indian society than the inculcation of traditional cultural

norms. The developing industrial ethos of India appears to encapsulate traditional values. The dominant principle of traditional economic rationality, for example, has been communal service. In modern India whilst profit making has become an important principle of economic rationality, communal solidarity is still considered to be of primary importance.

Whilst the primary activity in rural economy remains labour intensive agriculture, the extent of labour required is weak compared with traditional agricultural requirements. Industrialisation and urbanisation of rural areas with greater investment in social overheads (education, health and transport) have attracted the migration of traditional land based, rural families. Although labour for wages has become the dominant activity in urban life, employment arrangements are developed on the understanding that the relationship between the employee and the company is a lifetime relationship. The company, in effect, becomes a surrogate family providing the security that had been a function of the traditional family.

5.1.6 THE CULTURAL MATRIX

Indian culture is a mosaic composed of a multiplicity of religions and *Jati* (castes), embellished by a vast spectrum of local customs and regional traditions. The complexity of Indian culture is further complicated by differentials in the rate of acceptance of features of Western cultures. For these reasons writers have warned against making unqualified generalisations when referring to family and kinship in India (Dube 1965, Gupta 1979, Guzder and Krishna 1991,). However, some uniformity has been created by a broadly common criminal and civil code. Perhaps a more significant variable is indicated by Dube (1965). He suggests that a common thread through Indian society is the legacy of value-orientation from Indian classical tradition. Others (Kakar 1978, Guzder and Krishna 1991) affirm conviction of a profound relationship between Hinduism, with its related mythology, and the psycho-social profile of Indian character. Even within the new dynamics created by urbanisation and migration Hindu mythology continues to effect an influence on intrapsychic and sociocultural processes.

5.1.7 CASTE

One aim of political reform has been to adjust the individual's self perception from caste member to citizen. The objective is to raise the individual's status to that of an achieved position rather than a Sanskritised and ascribed position. By so doing the individual is encouraged to realise his/her own place in history. The reality appears to be that although there is political will to break free from the social restrictions of caste, they continue to exist in the Indian concept of identity (Nayar 1965, Sarma 1965, Das 1979, Gupta 1979, Kapur 1979).

The concept of *Jati* (caste) reflects the complex inter-relationship of apparently segmented Hindu society. It is an inter-relationship characterised by an ascribed system of status evaluation. In a hierarchical system each caste possesses specific historical, mythical, economic, political, religious and cultural associations. The ritual status of an individual is decided by the caste into which the individual was born. It is the responsibility of each caste to maintain its status by ritual observance calculated to preserve its individuality and purity. The significance of caste in the family context is that the natures of interpersonal and intrafamilial relations are as much governed by caste as is the structure of family and kinship.

Caste hierarchy is closely associated with occupational hierarchy, occupations being broadly categorised as "clean", "unclean" and "polluting". Accepting that there are many "open" occupations, there are distinct "caste" occupations passed from one generation to the next within specified castes. There are four vertically graded levels of social class at which castes function as isolable culture bearing units¹⁶.

16 Brahmins are considered an incarnation of Dharma. As guardians of divine power they are entitled to teach the Veda (Hindu scriptures). Brahmins are held to be the highest of all human beings. The Ksatrijas duty is the protection of the people whilst the Vaisyas responsibility is to maintain economic continuity through trade and agriculture. All three castes are of Aryan descent and as such are expected to sacrifice and study the Veda. The religious obligations of the Vaisayas are less rigorous than that of the other two classes. The Sudras are descendents of subjugated Dravinians. They are expected to serve the other classes by undertaking less favoured activities. However amongst the Sudras there is a division which allows the purer element to assimilate with higher classes whilst the Candalas are confined by their polluting activities which include sweeping and bearing corpses.

In the caste system, status evaluation on the ritual plane, as distinguished from economic or political status, is of supreme importance. The reason that there is very little evidence of vertical mobility from lower to higher ritual status is explained by the profound influence of the concepts of *Karma*, *Dharma* and *Maya* on the Hindu identity (Dube 1965). While the essence of *Karma* is fatalistic (i.e. that the present is governed largely by the past) *Dharma* is the path by which the individual may ensure a favourable future. *Dharma* is a prescribed way of life for the station of an individual and varies at each level of *Jati* hierarchy. The *Dharma* ideal is that within the parameters of the individual's status he should accept the interdependence of economic pursuits, worship and ritual, physical fulfilment and the quest for salvation.

Maya further strengthens the acceptance of preordained fate as it suggests that the material manifestation is not a reality but an illusion veiling the concerns to which humankind should be oriented. The Weberian concept of Hinduism is that it is escapist (Weber 1936). *Maya* directs Hindu thinking away from the toils of the material world to a higher plane of spiritual existence.

If Durkheim's perspective is right, the meaning of Hinduism for Indian society is profound. He reasoned that religion is never just a matter of belief, but that the essence of ritual observance is affirmation and heightening of a sense of group solidarity. It is upon such solidarity that the cohesion of society is dependent. This is clearly illustrated in the Indian family. Hinduism elevates the family as the channel through which the multifarious aims in life are to be realised. The value-orientations and structure of families vary according to the different strata of Hindu society. Accepting this diversity, it is the concept of the family and the individual components of it that is fundamental to Hindu society.

5.1.8 THE FAMILY

A common impression of Indian society is that it is characterised by the extended family. This impression has developed from legislation drawn from the *Mitaksara*¹⁷ which upholds the principle of a common ownership of property. As a response, the extended family pattern is perceived as an ideal (Gupta 1979). Perceptions of the extended family however need to be qualified. It appears that the typology of simple, compound and extended family cannot be used as a model to explain the organisation of the Indian family (Dube 1965, Payne 1977).

A cross sectional perspective of Indian family is likely to present a view of a transitional phase in family structure as the organisation of the family follows a cyclical pattern. Simple families, sometimes including adherants from an earlier extended family, develop into extended families. After the demise of parents there is an inevitable separation of married brothers (it is the norm for wives to be taken into the husband's home) as physical conditions dictate. Consequently the extended family again fragments into simple families. The structure of the family has been shown to be caste and economy dependent. The higher castes have demonstrated a stronger extended family tradition whilst the lower castes, through economic necessity, tend to fragment the extended family arrangement very much earlier than contemporaneous Sanskritised castes. In lower castes where women can be economically independent there appears to be less evidence of extended families.

The "joint family" is a preferred model used to describe the Indian family (Dube 1965, Gupta 1979). As a general term it broadly includes developmental stages, variable domestic arrangements and kinship systems. As such it encompasses situations including 3-4 generation extended families living together with shared responsibilities. It also applies to units wherein several families live as independent households sharing joint ownership and management of legally undivided property.

17 A 13th century legal treatise in the form of a commentary on an ancient verse compilation of traditional learning. Mitaksara is still referred to by the courts of India. The law relating to Hindu joint family property has been touched only marginally by The Hindu Succession Act and Hindu Adoption and Maintenance Acts of 1956.

The definition includes separate living but linearly related families united by the common ownership of ancestral land.

5.1.9 INTRA-FAMILY RELATIONSHIPS

Dube (1965) cites three major considerations affecting intra-family relationships:

- a primary acceptance of separate male/female roles
- assumptions regarding age
- the position in the scale of kinship.

Most relationships within the family are complementary. However, extending beyond the family into the intricacies of kinship, relationships become more reciprocal.

Child/parent relationships are essentially complementary until time reverses the father/son roles. The role of the daughter is different, she is trained for marriage.

Deviant female behaviour, or inadequacy in domestic training is considered a reflection of parental failure which lowers family prestige and gives a focus for critical estimation by prospective parents-in-law. After marriage a daughter is treated as a guest when visiting her parents' home. As a daughter-in-law however, she is subordinate to her mother-in-law. With passing of time the de facto control of domestic affairs is taken over by the daughter-in-law. Yet it is the mother-in-law who continues to hold the place of respect in the family. This is achieved because of her higher position in the scale of kinship.

5.1.10 GENDER ROLES

The fulfilment of *Dharma*, *Praja* (progeny) and *Rati* (pleasure) is by Hindu tradition, to be found within the sacrament of marriage. Accordingly individual interests are secondary to the supreme principle of familism. Kapur (1979) found that among educated and working women, the concept of marriage as a sacrament solemnised for the benefit of the family and socio-religious duty, was diminishing. However it appears that it is only the perspective that has changed and that marriage as an institution is not declining. It is apparent that a personal concept of marriage is in the ascendant. Women who voiced opposition to the value of marriage being primarily to

fulfil socio-religious need were the group emphasising their conviction that marriage was the vehicle by which personal fulfilment could be reached. In Kapur's opinion, the perceptions of the sanctity and purpose of marriage are assuming new dimensions (Kapur 1979). However, the need for marriage and the family is being increasingly felt among both modern and traditional Indian women. It was her conviction that as long as the woman's role in the family remains pivotal the institutions of marriage and the family will continue to be the stable core of Indian society (Kapur 1979).

Kakar (1978) insisted that the mythic roots of Indian identity could not be overestimated. This conviction is powerfully emphasised by Guzder and Krishna (1991). They have demonstrated the importance of matriarchal mythologies as an essential element in any examination of the dynamics of male and female interaction and particularly of the status of women in India (Guzder and Krishna 1991).

5.1.11 THE SHAKTI-SITA PARADIGM (Guzder and Krishna 1991)

Shakti personifies the central matriarchal figure central to Hindu mythology. She is considered the life giving procreative power of the universe, revealing at any one time a variety of personae demonstrating different aspects of her character. The image of Shakti represents an immensely powerful feminine primal force. It is the image of *Sita*, however, against which the Indian woman is examined. *Sita*, the archetype of the ideal Hindu wife, is portrayed in the *Ramayana*. She dutifully followed her husband into exile where her purity is indefatigable although she is greatly coveted and enticed by others. However the one fault she displayed was to be lured beyond the ring of protection drawn around her by Lakshman (Rama's brother). The event resulted in her abduction. Even though her integrity was never compromised and she remained chaste and devoted, the central dilemma of her life remained that she was unable to re-establish her purity in Rama's perception. Once stepped beyond the *Lakshman Rekha* (Lakshman's Ring), symbolic of patriarchal protection, the woman is condemned. Women without patriarchal protection are denigrated and perceived as worthy of abuse and insult (even widows may be considered symbolically castrated). Attaining motherhood is the only path by which a woman may elevate her status. It is

also in the combined identity as parents that the mutuality of husband and wife is achieved. The birth of a son ensures the perpetuation of the father's "self", it is the consolidation of masculine identity for the husband. For the wife the birth of a son ensures her a protected and esteemed position in the family. The image of Rama reflects the vulnerability of male status. Like Rama, a man is expected to honour cultural sanctions above any affection he may have for his wife in situations where doubt is cast on a wife's integrity. For this reason the mother-son relationship is highly esteemed. Beneath the protective umbrella of over-indulgent maternal care the bonding that develops between mother and son provides the mother with a security based on the son's dependence. The fear, awe and adoration displayed by the son reflects the reverence for *Shakti* the mother goddess.

Sita, as obedient, chaste and disciplined is the ideal role model of Indian femininity. In her purity she is promoted as daughter, mother and wife. Female purity is paramount in the context of food preparation, sexuality and social intercourse. As a powerful stabilizing feature, Hindu femininity never challenges Hindu masculinity or authority in the social hierarchy. The purity of *Sita* addresses the overt and covert needs and desires of men in the traditional family context by recognising and respecting the male mediated social order. There is an absence of female relationship roles in Hindu mythology. *Sita* has only a distant relationship with a remote and omnipotent Earth Mother. Even when her reputation is enhanced by bearing sons she is entirely dependent on the protection and benevolence of family men: *Rama*, her husband, *Lakshman*, her brother-in-law and her father-in-law.

Although contemporary developments have wrought changes, the covert norms, in Dube's opinion, have not changed to any appreciable extent. The general perception of the relative statuses of the sexes remains that the male is more desirable than, and qualitatively superior to the female. Hindu ritual considerations confirm the essential role of the male to complete all the rites and ceremonies prescribed by *Dharma*. However there are further practical considerations favouring the desirability of male offspring. Sons are expected to live with the family enhancing family prestige and prosperity as well as providing support for aged parents. While a daughter's affection

and tenderness are recognised, she cannot fulfil the role of a son. A daughter is considered a guest in her parents home where it is a parental obligation to prepare her for *Kanyadaam* (the gift of a virgin to the family of the groom). It is not uncommon for a daughter to be considered a visiting goddess who will bring prosperity to the parental home. Perceived in this way the financial burden of upbringing is viewed with less displeasure.

Dube (1965) has suggested that in the context of India's pollution/purity conscious culture the susceptibility of women to defilement, from which purification is difficult is significant. He explained that the male is not as easily defiled as the female. This ritual superiority of the male strength appears to have manifest and latent dimensions that cause and perpetuate double standards of morality. Because the male is relatively pollution resistant he has access to freedoms denied to women. It is this assumption of male strength that perpetuates the principle of male dominance and female dependence. Within the parameters of male dependence and domestic security, Dube (1965) suggests that the sphere of female freedom continues to be strictly limited.

Dube (1965) explains that assuming full responsibility for the protection and support of his family, a man's masculine virtues are justified. Where a man is dependent on women or children for support he is considered inadequate. It is his responsibility to control and discipline women and children in an atmosphere of co-operation and goodwill. Lapses in acceptable social behaviour demonstrated by women or children are considered a reflection of inadequate male dominance which leads to community censure of the male. Men are also expected to avoid social criticism by rejecting roles or functions culturally defined as feminine. Consequently women are left relatively free in their prescribed sphere.

5.1.12 THE INDIAN FAMILY STRUCTURE

Dube (1965) declared that it was unrealistic to evolve a representative family typology. He was cautioned by the complexity of Indian society (perhaps more realistically described as a conglomerate of societies) in which family organisation is

so highly variable. However, he does suggest that there are three broad categories by which Indian families can be described:

Tribal and lower-strata rural and urban family

Upper-strata rural family and traditional upper-strata urban family

Progressive urban family.

Others have also used these categories when describing social structures. (Gupta 1979, Kapur 1979, Das 1979).

Dube (1965) observed that a significant section of tribal peasantry has adopted the social norms of upper-caste Hindus. Furthermore, upper-castes in the lower economic strata characteristically observe cultural norms to a greater extent than lower castes in the same economic strata. This observation demonstrates the limitations in generalising features of the group. However, by describing common or dominant characteristics, it is reasoned that variables relative to this field of study can be identified.

Leprosy is a disease of the lower socioeconomic groups (Kartikeyan and Chaturvedi 1979, Mehta et al. 1992) and as such it is most keenly experienced by the first group Dube (1965) described (i.e. Tribal and lower-strata rural and urban families).

5.1.13 TRIBAL AND LOWER-STRATA RURAL AND URBAN FAMILY

There are no clearly distinguishable spheres of activity characterising this family type. Although both men and women earn to provide for their families' needs, women are assigned less rigorous indoor tasks. Domestic management and child care are female responsibilities. Women are expected to participate in economic activity but it is the responsibility of the men to undertake the greater share in earning. In rural communities women may earn daily wages as labourers or may be expected to undertake traditional family crafts. If the family has agricultural land the women are expected to assist in the general upkeep of the land. In urban situations a woman's role in the family demonstrates a more defined traditional calling. Alternatively she may be employed as a domestic or a manual labourer. Older children and men may

take responsibility of child care only if the women are incapacitated (Dube 1965).

Families of this type are by necessity self sufficient. In periods of illness relatives and neighbours may help if work, ordinarily shared by family members cannot be undertaken. After a short phase in their role as daughter-in-law, women participate equally in the social and religious life of the community. Only if there is suspicion of infidelity are the activities of the daughter-in-law kept under scrutiny. However it appears that the stereotype routine disadvantages unusual initiatives. This restriction extends to recreation and participation in community and national events. Religious festivals and marriages provide the only significant diversions from the monotony of daily routine (Dube 1965, Kapur 1979).

Authority is a reflection of age and kinship status. Most families on this level are, however of the simple type. Although decision making is a jointly shared responsibility male authority is regarded as superior. Where there is a requirement to make decisions regarding the sale of property or negotiating marriages, elders of the kin group expect to be consulted (Dube 1965).

5.1.14 INTERVIEW RATIONALE

The author suggests that acceptability may be indicated by attitudinal variables and that if attitudes to the intervention were consistently positive it may be inferred that the treatment was acceptable (Proctor 1993). It is suggested here that the validity of this construct is dependent on two factors:

1. Evidence to support the suggestion that the attitudes reflected were associated with the intervention and were not affected by confounding variables.

Confounding variables may include:

Significant life events (Holmes and Rahe 1967)

Causal and recovery beliefs (Dalal and Singh 1992)

Perceived social desirability (favoured status associated with being "chosen" for treatment).

2. An association between attitude and an observable measure related to

attitude.

(The criterion measure used was perceived changes in individuals' approach to participation in social activities. The aspects of social participation considered in this study are social activities previously examined by Rao [1992].)

An interview schedule was designed to investigate two issues. The first was whether the efficacy of the treatment was affected by differences in self administered foot care procedures. The section of the schedule designed to address this issue was also used to gather opinions of foot care recommendations. The second issue related to the attitudes of the study sample to orthotic intervention. This was a more complex issue and required the analysis of a number of related variables.

Although the two major issues (behaviour and attitude) are related they were considered independently. To accomplish this aim the schedule comprised two discrete sections. These sections were referred to as "The Foot Health Schedule" and "The Attitude Profile". In this chapter each section is presented separately but features from both sections are presented in the general discussion which concludes the chapter.

5.1.15 THE FOOT HEALTH SCHEDULE

The foot health schedule was designed to investigate two issues:

1. The association between foot health care behaviour and plantar ulceration.

Rationale

The hypothetical construct (i.e. ulcer prevention through self foot care) is widely advocated (though not empirically tested) in the literature (Watson 1986, ILEP 1993). On this basis, the strength of an association between behaviour and the absence, or presence, of ulceration should be established. It was considered that subjects with ulceration may have declared poorer self care procedures than subjects without ulceration. An implication of such a finding would be that other findings may have been biased by differences in health care behaviour. It is acknowledged that the

criterion measure (ulceration) is not a perfect indicator as there are causes of ulceration other than poor self care.

2. The association between foot health care behaviour and opinions of foot health care recommendations.

Rationale

Accepting that the responses recorded are valid, an examination of the association between opinions and self care practice will yield a perspective of the attitude/behaviour relationship that exists amongst the study population. It is not within the scope of this study to investigate the circularity of the attitude/behaviour relationship. Indeed the complexity of the relationship is recognised as a limitation to the conclusions that may be drawn from analysis.

5.2 METHOD

To compose the Foot Health Schedule, several statements relating to foot care were formulated from "Disability prevention in leprosy patients" (Watson 1986). These statements were then condensed to form succinct questions to limit the effects of interview schedule length (Bradburn and Sudman 1979a). By composing a limited, but homogenous set of questions it was reasoned that reliability would not be compromised.

Questions encapsulating key concepts of patient self care procedures were formulated. The aim was to record opinions and reported practice of foot care requirements independently.

The first section of the questionnaire assessed opinions (related to knowledge of health care procedures). In the second section the questions were repeated, in a reworded form, using a direct approach. A clear intention to discern the respondents' actual foot health behaviour was not disguised in the latter section of the schedule.

The foot health schedule was piloted in March 1994 following which adjustments were made. The schedule was then incorporated into the broader schedule including attitudinal questions and was used to collect responses from the study sample in January 1995. (See Appendix 3)

5.2.1 TRANSLATION AND INTERVIEW PROCEDURE

A group of fluent Marathi and Hindi speakers was recruited (one from the student body at Queen Margaret College and three from Dr Bandorawalla Leprosy Hospital). The schedule was presented to two speakers representing one of each of the languages. These interpreters were requested to translate the questions into their respective languages. The completed schedules, in translation, were presented to two other translators who were requested to translate the questions back into English. The translated schedules were then compared with the original schedules in English.

The schedule that had been translated into Hindi was criticised at three points where it was considered that the gestalt of the questions was not adequately conveyed. Following consultation, adjustments to the questions were made in Hindi and the revised questions were again submitted for translation. The revised questions, when translated back into English, were considered an appropriate interpretation. (See Appendix 3.)

An English speaking physiotherapy technician (Mr R Shedad), disadvantaged through leprosy and living amongst the study population, was trained to conduct the interview procedure. The interviews were conducted in unthreatening environments (in the hospital grounds, in subjects' homes or at venues where the subjects commonly congregate socially). It was considered that this approach would minimise interviewer and response bias.

A majority of respondents were illiterate. For this reason all questions were conveyed verbally. The interviewer retained a copy of the schedule upon which he recorded responses. Forty-six subjects agreed to be interviewed. At the end of each day on which interviews had been conducted, completed schedules were submitted to the author so that the procedure could be monitored. Daily communication between the interviewer and the author presented opportunities to discuss issues related to the execution of the interview schedule.

5.2.2 SCORING AND CATEGORISATION OF RESPONSES

The scaling of responses was based on the generally held opinion that recommended procedures will enhance the subject's prospects of wound avoidance (Watson 1986). The terms chosen to categorise the responses imply that opinions and/or behaviours may be correct or incorrect in their orientation. This is intentional as disagreement with recommended procedures is likely to compromise the foot of the subject.

Response Rating

Of the twelve questions asked in each section, ten were designed so that responses could be correlated to ascertain the relationship between opinions and behaviour.

Opinions

There were twelve statements in the first section. To each statement subjects were requested to respond by identifying an opinion most closely concurring with their own.

Opinions Suggested were:

Strongly Disagree Disagree Uncertain Agree Strongly Agree

Responses were categorised as:

Favourable (coded +2) Denoted opinions which were compatible with recommended principles.

Mediocre (coded +1) Denoted responses where the opinions reflected approached compatibility with recommended principles.

Noncommittal (coded 0) This code denoted uncertainty

Poor (coded -1) Denoted a mild disregard for recommended principles

Adverse (coded -2) Denoted opinions opposed to recommended principles.

Behaviour

There were twelve questions in the second section. To each question subjects were requested to identify an appropriate response:

Not Applicable Daily Once a week Once a month Never

Responses to questions relating to foot care behaviour were categorised as:

Favourable (coded +2) Denoted behaviour which was compatible with recommended principles.

Mediocre (coded +1) Denoted responses where the behaviour suggested approached compatibility with recommended principles.

Noncommittal (coded 0) This code denoted nonapplicability or vagueness.

Poor (coded -1) Denoted a mild disregard for recommended procedures.
Adverse (coded -2) Denoted behaviour at variance with recommended procedures.

5.2.3 STATISTICAL ANALYSIS

χ^2 Test of Association and Spearman's correlation coefficient for ranked data were used.
(The assumptions associated with these tests were discussed in section 2.2.3.)

5.2.4 SAMPLE DETAILS

The social background of the study population was detailed in chapter 2.

Healed Group = 24	8 Female	16 Male
Unresolved Group = 22	5 Female	17 Male

Each subject scored twelve variables in the "behavioural" section and twelve variables in the "opinions" section.

5.3 RESULTS

5.3.1 TEST 1: THE ASSOCIATION BETWEEN FOOT HEALTH CARE AND ULCERATION

H₀ Subjects with plantar ulceration did not differ in their responses, relating to foot care behaviour, from subjects without plantar ulceration (see Fig.30). Data were collapsed to facilitate Fisher-Irwin's Exact Test. Responses categorised as "mediocre" were excluded from analysis.

Table 31: Comparison of behaviour

Questions	Responses				Analysis	
	Healed		Unresolved		χ^2	P Value
	+	-	+	-		
Question 1	19	3	19	1	0.96	0.34
Question 2	16	3	18	2	0.31	0.58
Question 3	14	7	14	7		No Difference.
Question 4	23	1	22	0	0.93	0.33
Question 5	20	3	19	3	0.003	0.95
Question 6	19	3	19	3		No Difference
Question 7	19	3	20	1	3.11	0.08
Question 8	23	1	22	0	0.94	0.33
Question 9	17	7	16	6	0.02	0.88
Question 10	21	3	20	1	0.82	0.36
Question 11	14	13	17	25	0.85	0.35
Question 12	24	0	22	0		

No significant differences were found between the two groups.

5.3.2 TEST 2: THE ASSOCIATION BETWEEN OPINIONS OF FOOT HEALTH CARE AND ULCERATION

H₀ Subjects with plantar ulceration did not differ in their opinions of foot care recommendations, from subjects without plantar ulceration.

Data were collapsed to facilitate Fisher-Irwin's Exact Test. Responses categorised as "mediocre" were excluded from analysis.

Table 32: Comparison of Opinions

Questions	Responses				Analysis	
	Healed		Unresolved		χ^2	P Value
	+	-	+	-		
Question 1	15	9	11	9	0.25	0.61
Question 2	19	3	19	3		No Difference
Question 3	12	11	13	9	0.21	0.64
Question 4	19	1	19	3	0.9	0.34
Question 5	16	8	16	4	0.9	0.32
Question 6	17	7	22	0	7.56	0.005
Question 7	15	3	20	1	1.49	0.22
Question 8	23	1	22	0	0.93	0.33
Question 9	0	11	1	8	1.28	0.25
Question 10	19	4	22	0	4.19	0.04
Question 11	8	15	8	13	0.05	0.81
Question 12	11	4	10	2	0.38	0.53

5.3.3 TEST 3: THE RELATIONSHIP BETWEEN OPINIONS AND BEHAVIOUR

It was decided that for the purpose of examining the relationships between variables, responses could be considered to have been contributed by a homogenous group. Justification for this decision is that there were only two differences found between groups when compared on all variables. The two variables found to have been different were excluded and not considered in this analysis.

Table 33: Relationships between Opinions and Behaviours: n = 46
Spearman's Rank Correlation 95% Confidence.

Related Questions		Total scores for each rating					R _s	P Value (2 tailed)
		+2	+1	0	-1	-2		
1.	Behaviour	7	31	4	4	0	.15	0.32
3	Opinion	1	24	1	19	1		
2.	Behaviour	6	28	7	5	0	.42	0.001
4	Opinion	37	1	1	1	6		
3.	Behaviour	8	20	4	13	1	.3	0.01
5.	Opinion	31	1	2	2	10		
6.	Behaviour	28	10	2	6	0		
8.	Opinion	45	0	0	0	0		
7.	Behaviour	15	24	3	4	0	.54	0.001
7.	Opinion	31	4	7	3	1		
9.	Behaviour	15	18	0	11	2 2	.03	0.45
11	Opinion	15	1	2	26			
10	Behaviour	37	4	1	3	1	.45	0.001
12	Opinion	18	4	18	4	2		
11	Behaviour	7	24	12	2	1	.26	0.07
1	Opinion	14	12	2	8	10		
12	Behaviour	46	0	0	0	0		
2	Opinion	16	23	1	5	1		

5.3.4 Limitations

Small coefficients can be misleading. Whilst measuring the extent of a monotonic relationship they ignore the possibility of non-monotonic relationships. It is accepted that an effect of monotonicity is that there will be a limit to the inferences that can be made. The coefficients given will not indicate whether relationships are linear or not. For this study this limitation is acceptable. Data were only used to describe whether ranked responses demonstrate that scores for opinion were related to scores for behaviour and the general direction of relationships. For these purposes the choice of Spearman's rank correlation is appropriate.

5.3.5 Summary of the Foot Health Schedule results

The findings of the foot health schedule demonstrated that there were no significant differences between the "Healed" and "Unresolved" groups when compared on twelve behavioural variables. There were two differences between the groups when compared on twelve variables of opinion. These results suggest that ulcer resolution was not biased by differences in health behaviour.

Consideration of the relationships between opinions and behaviours suggests that opinions do not reflect behaviour related to the same issue. The relationship between opinion and behaviour appears complex. The "sick role" adopted by the leprosy impaired appears to confound the Parsonian explanation which would suggest that the leprosy impaired would accept the "wisdom" of recommendation but not be able to comply with the requirements suggested. These results demonstrate a converse relationship: i.e. that behaviour was generally better than opinions may have suggested. It is suggested that this apparent paradox may be an effect of stigma. This issue is pursued in more depth later.

5.4 DISCUSSION

This discussion will focus on an interpretation of the results. Methodological issues and further inferences from the results, considered in the context of the literature, will feature in the General Discussion.

An aim of the foot health care schedule was to investigate whether the efficacy of the treatment was affected by differences in self administered foot care behaviour. The responses from subjects with healed ulcers were compared with those from subjects with unresolved ulcers. It was found that the behaviours and opinions of the subjects interviewed were generally positive and that there were no significant behavioural differences between the two groups. This finding suggests that earlier results (demonstrating efficacy) were unlikely to have been biased by variations in health care behaviour.

The absence of differences between groups may be considered counter-intuitive. It might have been expected that subjects without ulceration would have reported behaviour and opinions significantly more positive than subjects with ulceration. (The rationale for foot care education is primarily that it should be an aid to the prevention of ulceration.) Only two variables yielded significantly different results. Both variables related to opinions of footwear issues.

On the "opinion" schedule, the sixth statement suggested that it was not important for leprosy patients to wear leprosy sandals to prevent ulcers. (Strong disagreement with this statement would attain the highest score.) It was recorded that all subjects with unresolved ulcers disagreed with the statement whilst seven subjects in the "healed" group agreed with the statement. A similar finding was recorded for the tenth statement which suggested that "footwear from the market is better than leprosy footwear for preventing ulcers". None of the subjects in the "unresolved" group agreed with this statement whilst four subjects in the "healed" group did.

The question of footwear is sensitive. The black micro-cellular rubber leprosy sandals

are considered highly stigmatising but not as stigmatising as ulceration. It is possible that subjects without ulceration may attempt to distance themselves further from the image of leprosy by suggesting that less stigmatising forms of footwear were an acceptable alternative. For subjects with unresolved ulcers, it may have been that the stigma of footwear was not as significant as the stigma of ulceration. It was interesting to observe that seven subjects suggested that leprosy footwear was not as effective as other forms of footwear. However, only three subjects from that group chose to wear alternative footwear (question 5 on the "behaviour" schedule). It was also recorded that three subjects with unresolved ulcers chose not to wear leprosy sandals. It could have been the case that the cost of alternative footwear was prohibitive. However even for those who had access to such alternatives, the choice was not to abandon leprosy sandals completely. Alternative footwear was not worn to the total exclusion of leprosy sandals, for all but one subject declared that they did wear leprosy sandals, at least occasionally. No subject ever ventured from his/her home without footwear of some type. The apparent dichotomy suggested by these results was more defined in the third test where opinions were correlated with behaviours related to the same issues.

5.4.1 THE RELATIONSHIPS BETWEEN OPINIONS AND HEALTH BEHAVIOUR

The Foot Health Schedule was also used to gather data to describe the relationship between foot care behaviour and opinions of foot care recommendations. By so doing a context for discussion of attitudes and the possible factors that influence them could be enhanced.

The Hypothesis

It was thought unlikely that subjects would comply with any recommendation considered to have scant merit. It was considered, therefore, that scores for behaviour would correlate positively with scores for opinions of behaviour recommendations. This hypothesis was found not to be correct. Family and employment commitments, and motivation were variables likely to confound strong correlations. However, only

four results yielded coefficients significantly different from no correlation¹⁸. A broad impression from the results is that although opinions related to recommendations were frequently negative or noncommittal, the behaviour associated with the same recommendations was relatively positive. These results may indicate acquiescence to a powerful external locus of control. Passive obedience may be an indication of the loss of self esteem and self blame (these issues are addressed in the General Discussion).

5.4.1.1 Walking sticks and ulcer dressings

28 subjects disagreed that it was important for patients presenting with ulcers of a 2.5cm. diameter to use a walking stick. However, all but two suggested that they would consider using a stick for ulcers of a diameter less than 2.5 cm. Similarly, 18 subjects indicated that they were not sure whether it was important to dress wounds. A further 6 indicated their contention that wounds need dressing only if they are greater than 1cm in diameter. All but 4 of these subjects indicated that they routinely dressed wounds of less than 1cm in diameter. These responses are similar to that cited above concerning foot wear. Subjects may have wished to distance themselves from the stigmatising images of walking sticks and dressings by denying that they may be essential aids. The apparent opinion /behaviour dichotomy may be an indication of poor psychological adjustment (this issue, and the pathology of stigma are discussed later).

Interestingly the statement that attracted unanimous strong agreement, was the suggestion that patients should check their footwear for damage. The rationale for this recommendation is that damaged footwear is likely to be harmful. It may be, that in the perspective of the leprosy impaired, damaged footwear is even more stigmatising than sound footwear.

18. These findings must be considered with caution as they do not imply a high correlation between variables. They do indicate that the null hypothesis of zero correlation is consistent with the data, but because the sample was large ($n = 46$) small values will be highly significant. Values around $r = .4$ indicate little more than a loose relationship between variables.

5.4.1.2 Skin care

20 subjects indicated that they did not consider it important to routinely apply oil rubs but only 4 applied oil less frequently than once a month (4 more indicated that the recommendation did not apply to them. This finding is an indication of noncompliant behaviour because all subjects participating presented with neurological impairment.

There were slight correlations describing the relationships between opinions and behaviours relating to "foot soaks" and "hard skin" removal respectively. These do not support the phenomenon of poor opinion but sound compliance. The majority declared a high opinion of these procedures but also declared sound compliance. It is still noteworthy that 10 subjects strongly disagreed that hard skin removal was important and 6 strongly disagreed that foot soaks had any benefit. The results demonstrate that all but 1 subject complied to some extent.

These activities are essentially private and are conducted in a similar fashion to acts of personal hygiene. As such they are unlikely to be considered stigmatising agents. This may explain why they were considered to have greater merit than measures discussed earlier.

5.4.1.3 Walking and rest

A statement regarding the importance of rest attracted varied responses. 18 subjects indicated that they disagreed that rest was important whilst 22 agreed with the statement. 31 subjects indicated that they did make some conscious effort to rest their feet, but 12 indicated some indifference by responding that they did not often consider rest. An indication is that there was still a greater level of compliance than opinion may have suggested.

Responding to the question regarding the recommendation to moderate walking, all subjects indicated that they made an effort to comply with the requirement. Even on this issue 6 subjects disagreed that it was an important recommendation.

5.5 THE ATTITUDE PROFILE: A SEMI-STRUCTURED INTERVIEW

This aspect of the interview schedule was so designed that data, describing attitudes amongst the study sample, could be collected.

5.5.1 METHOD

Since the treatment group was unique it was not possible to pilot this component of the study. Appropriate questioning was developed following discussion with senior medical staff at Dr Bandorawalla Leprosy Hospital, sociocultural observations, informal interaction with patients and consideration of similar research conducted by Rao (1992). (For translation and interview procedure see section 5.2.1.)

5.5.1.1 Sample details

Of the 59 subjects who presented for ulcer assessment 46 agreed to be interviewed. Of this number 22 agreed to have a verbal response recorded on audio tape (others either declared that they had nothing to add, or indicated that they found the technique threatening).

Interviewed Subjects:

Experimental Group	n = 22		
	Healed = 14	4 Female	10 Male
	Non Healed = 8	1 Female	7 Male
Control Group	n = 24		
	Healed = 10	5 Female	5 Male
	Non Healed = 14	3 Female	11 Male

5.5.1.2 Procedure for analysis

An initial indication of attitude toward the treatment was described by analysing responses to Question 3:

"If you think these devices could be useful, or harmful, for other people, what sort of people do you have in mind?"

By describing the responses to this question an indication is given of prevailing attitudes towards the intervention.

To support the validity of the suggestion that the attitudes expressed were associated with the intervention, responses to question 4 were analysed.

Question 4: *"What did you expect when you were first given the device?"*

(The probes listed below were suggested. Following a dichotomous response to each probe further response was sought to ascertain the strength of feeling associated with the response.)

1. *"Was quicker healing expected?"*

"How do you feel about the time it took / is taking to heal?"

2. *"Was recurrence expected?"* (asked only of those with healed ulcers)

"How do you feel about that?"

3. *"Did you realise that continued use would be necessary?"*

"How do you feel about that?"

Responses to question 2 were also analysed to ascertain whether subjects had experienced any problems with the devices supplied. Where subjects indicated that they had experienced problems, further probes were used to gauge the severity of the problems as perceived by the subjects. This data was used to ascertain the effects of problems experienced on the attitudes reported.

Question 2: *"Have you had any problems with the device?"*

Responses to question 7 were analysed to ascertain whether there had been observable changes in the manner in which subjects approached participation in social activities.

Question 7: *"Are there things you can or cannot do now, since your ulcer was treated?"*

Six variables were examined:

Travel	Marketing	Public Worship	Work
Eating in Public places	Attendance at Public Events		

For each activity of interest the respondents were requested to indicate whether their participation was:

Greatly Improved	Improved	No Different	Worse	Much Worse
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Questions 1, 5 and 6 were presented to ascertain whether the attitudes expressed were affected by other variables.

Question 1: *"What important things have happened in your life over the last twelve months?"*

Question 5 and 6 were excluded from analysis due to poor response (discussed later).

Results analysis and discussion follow independent investigations. The chapter is culminated by a discussion in which indications from interview findings in general are presented. Independent investigations include:

1. Attitude to treatment as indicated by expectation/opinion of healing.
 The effects of treatment problems on attitude.
2. The relationship between participation in social activities, ulcer healing and attitudes to the intervention.
3. The association between changes in perceived improvements in social activities and attitudes to the intervention.
4. The effects of social variables on attitudes to the intervention.

5. The association between ulcer resolution and significant life events during the experimental period.

5.5.2 RESULTS

5.5.2.1 Test 1: Attitude to treatment as indicated by the recommendation that the treatment should be extended to others.

Subjects were encouraged to offer an opinion on the suitability of the treatment for others. Having identified any particular group, the subjects were then encouraged to express their strength of feeling.

Two subjects declined to comment on the grounds that they would not use the orthoses and would therefore not recommend that others should. Four others did not comment because they did not feel confident that their opinions on this matter would be valid.

Although all subjects were encouraged to specify groups for whom the treatment would be either indicated or contra-indicated, only one subject demonstrated sufficient confidence to make specific recommendations. All other subjects indicated that their opinion related to "all" sufferers. No clear indication can be given whether "all" refers to patients with sensory loss, ulceration or leprosy per se. Clearly, for the population generally, characteristic impairment, deformities and ulceration remain indications of leprosy whether the disease is cured or not.

Forty Subjects responded to this question:

One subject indicated that in his opinion orthoses would be "harmful" to others.

Sixteen subjects indicated that, in their opinion, orthoses would be "helpful" for "all" sufferers.

Twenty-two subjects suggested that orthotic treatment was "essential" for "all" sufferers.

Analysis

There was only one negative response. Consequently groups could only be compared on two positive variables. Using χ^2 Test it was ascertained that there were no differences in opinion between subjects with healed ulcers and those with unresolved ulcers, or between control group subjects and experimental group subjects.

**Table 34: Recommendations for extension of treatment to others:
 Comparing opinions of healed and unresolved groups**

	Essential	Helpful	Total
Healed	12	10	22
Unresolved	11	6	18
Total	23	16	40

$\chi^2 = 0.41$
P =0.52

**Table 35: Recommendations for extension of treatment to others:
 Comparing opinions of control and experimental groups**

	Essential	Helpful	Total
Control	12	7	19
Experimental	11	9	21
Total	23	16	40

$\chi^2 = 0.26$
P =0.60

5.5.2.2 Test 1: Discussion

The most distinguishing feature of the data relating to responses to this question was that all but one response was positive. The enthusiasm to extend the treatment to others appears not to have been affected by ulcer resolution or group designation. The attitudes expressed appeared to be associated with the intervention per se as recommendations were forthcoming from subjects within either group, whether their ulcers had resolved or not. .

The positive nature of responses suggests that the intervention was endorsed by the high opinions of the subjects on the issue of recommendation. The study population demonstrated a positive attitude to the intervention. However it was recognised that the opinions reported were likely to have been influenced by other factors. The promotion of the subjects' sense of self worth and human dignity as an effect of the provider / receiver relationship that developed over the course of the trial period may have been significant (such issues are presented in the General Discussion).

A bridging of the "untouchability gap" (Berreman 1984) was unlikely to have been perceived as serving the self interest of the researcher. If it was considered by the subjects to have been essentially altruistic, the treatment act rather than the form of treatment , may have had a significant impact on the psychosomatic well being of the subjects. An objective, therefore, was to ascertain whether the attitudes expressed reflected attitude toward the treatment providers or whether they were a bona fide reflection of attitude towards the intervention. For a valid impression of "attitude to the intervention" to be presented, responses to further indicators of attitude are reported below. By so doing the probability of displaying an idiosyncratic component was reduced (Moser and Kalton 1971).

5.5.2.3 **Test 2: Attitude to treatment as indicated by expectation / opinion of healing rate.**

Subjects were encouraged to make an initial dichotomous response to indicate whether they had *expected* healing to be quicker. If it could be demonstrated that subjects with healed ulcers responded to the question differently from subjects with unresolved ulcers it may be suggested that the "expectation" responses were biased by contemporaneous ulcer status.

The effect of ulcer status on expectation.

H₀ Subjects with healed ulcers responded differently to subjects with unresolved ulcers.

Healed n = 25 Unresolved n = 21

Analysis

Table 36: Comparing expectation of quicker healing: Healed vs. Unresolved.

	Yes	No	Total
Healed	8	17	25
Unresolved	10	11	21
Total	18	28	46

$\chi^2 = 1.16$
P = 0.27

Expectations expressed by the respondents in the *Healed Group* were not significantly different from those expressed by respondents in the *Unresolved Group*. *H₀* could not therefore be rejected. An implication of this finding is that the expectations reported do not appear to have been biased by ulcer status at the time of reporting. The responses may therefore be a valid representation of subjects' recall of

expectations relating to the time it took (continued to take) for their ulcers to heal. It is accepted that the concept of "recall" is problematic. The expectations reported may not be a representation of expectations at the time of orthotic supply.

Qualified responses.

Subjects were requested to qualify their dichotomous responses by identifying an attitudinal category which most closely reflected their feelings regarding the healing rate they had experienced. (The probe was: "How do you feel about the time it took / is taking to heal?")

Table 37: Categorisation of responses to expectation of healing n= 46

Expected Quicker Healing	Delighted	Pleased	Accept.	Disappointed	Annoyed	Total
Yes	0	4	10	4	1	19
No	6	17	4	0	0	27
Total	6	21	14	5	0	46

5.5.2.4 Test 2: Discussion

58.7% of all subjects did not expect faster healing than that which they had experienced. Those who had not expected faster healing ($n = 27$) were more positive in their responses to the question. However, of those subjects who had expected faster healing ($n = 19$) only five subjects expressed disappointment at the outcome.

The attitudes reported were either an effect of the intervention, an effect of recalled expectation or an effect of an interrelationship between the two variables. The most likely event is that the responses represent the interrelationship between the two variables. It was demonstrated that subjects who did not expect healing to be as quick as that experienced, were more positive in their responses. This effect may be an expression of pleasure relative to the unexpected nature of the event. However this apparent inverse relationship was not repeated amongst subjects who had expected faster healing: these subjects ($n = 19$) reported only 5 negative responses.

Seven subjects, with unresolved ulcers at the time of interview, expressed that they had not expected quicker healing. However, when asked to qualify their responses they declared that they were "pleased" or "delighted" with the healing rate they had experienced. This was an important sub group because it cannot be claimed that their responses were affected by confounded expectation, as their ulcers had not healed. Their indication of positive satisfaction was considered to be attributable to the intervention.

The findings do suggest that the responses made could be attributed to attitude to the intervention however it is probable that the results were not exclusive of expectation effects.

5.5.2.5 **Test 3: The effects of group allocation on expectations and attitudes**

Data was available to test the hypothesis that expectations of healing, and attitudes to treatment were affected by the allocation of subjects to groups, and consequently, by the technical personnel: i.e. The Indian technician (*Control Group*) or me (*Experimental Group*).

Responses from *Experimental Group* Subjects were compared with those from *Control Group* subjects.

Experimental Group n=22
14 presented with healed ulcers, 8 presented with unresolved ulcers.
Control Group n=24
11 presented with healed ulcers, 13 presented with unresolved ulcers.

Table 38: Expectation of quicker healing: Experimental vs. Control.

	Yes	No	Total	
Experimental	10	12	22	$\chi^2 = 0.03$ $P = 0.58$
Control	9	15	24	
Total	19	27	46	

There was no significant difference between dichotomous responses to the question relating to the expectation of quicker healing. This result suggests that expectations were not affected by the allocation of subjects to groups.

5.5.2.6 **Attitudes toward healing rate: Experimental versus Control groups**

Further investigation proceeded to examine whether attitudes in the *Experimental Group* were different from those in the *Control Group*.

H₀ There were no differences in attitudes relating to healing rate between the Control Group and the Experimental Group.

Table 39: Attitudes : Experimental group compared with Control group.

	Delighted	Pleased	Acceptance	Disappointed	Annoyed	Total
Experimental	4	9	6	2	0	21
Control	2	11	8	3	1	25
Total	6	20	14	5	1	46

Analysis.

Data were collapsed to facilitate Fisher Irwin's Exact Test (responses categorised as "Acceptance", n = 14, were considered neutral and were not included in analysis).

Table 40

Attitudes : Experimental group compared with Control group:Fisher Irwin's Exact Test.

	Positive	Negative	Total	$\chi^2 = 0.54$ P = 0.46
Experimental	13	2	15	
Control	13	4	17	
Total	26	6	32	

Using the Fisher - Irwin Exact Test, the attitudes towards healing rate expressed by the respondents in the *Experimental* group were found not to be significantly different to those expressed by respondents in the *Control* group. This finding does not permit the rejection of H_0 , it may therefore be surmised that being designated into either group did not affect the subjects' attitudes, related to expected healing rate.

5.5.2.7 **Test 3: Discussion**

It was considered that the treatment would affect discrete attitudes that could be linked directly with the intervention thereby indicating relative levels of acceptability. A retrospective assessment of attitudes, as affected by expectations of healing, were examined. It is accepted that had subjects been surveyed before the intervention, responses recorded as "expectations" would have had greater validity. However, it was demonstrated that the expectations expressed were not influenced by ulcer status at the time of questioning.

It was also demonstrated that attitudes were not affected by the allocation of subjects into either the experimental or control groups. An implication of this finding was that the results were not biased by perceived differences in the expertise or character of either the Indian technician or me.

5.5.2.8 Test 4: Attitude to treatment as indicated by the realisation / opinion of the requirement to wear the prescribed devices continuously.

Subjects were encouraged to indicate whether they had realised that the devices supplied should be worn as a continuous adjunct to other measures of foot care (this point was communicated to each individual at the time of supply). It was considered that subjects with healed ulcers would be more aware of this requirement than those with unhealed ulcers. An hypothesis suggesting that healing was associated with effective communication, or an acceptance of treatment requirements, was generated.

H₀ Ulcer resolution was not associated with a realisation of the need for continuous use of the devices supplied.

Healed n=25
Unresolved n=19

(Two subjects with unresolved ulcers declined to answer this question. They had both rejected the treatment.)

Table 41: Comparing realisation of treatment requirement: Healed vs. Unresolved

	Yes	No	Total
Healed	18	7	25
Unresolved	10	9	19
Total	28	16	44

$\chi^2 = 1.75$
P = 0.18

The differences in responses between the Healed and Unresolved groups were not significant and H_o was consequently not rejected. An implication is that healing may not have been associated with a sense of individual responsibility, which may have affected the outcome of the intervention. An hypothesis was developed as a consequence of this finding. It was suggested that where treatment requirements had either been inadequately communicated, or rejected, attitudes toward the treatment would be different to those declared by subjects who had understood and accepted treatment requirements.

H_o *There were no differences in attitudes between subjects who had not understood, or rejected, treatment requirements, and those that had accepted them.*

Table 42: Comparing Attitudes Towards Treatment Requirement

Understood	Delighted	Pleased	Acceptance	Disappointed	Annoyed	Total
Yes	2	8	17	2	0	29
No	1	3	6	4	1	15
Total	3	11	23	6	1	44

Data were collapsed to facilitate Fisher Irwin's Exact Test. Responses categorised as "acceptance" were considered neutral and were not included in analysis.

Table 43: Attitudes Towards Treatment Requirement: Fisher Irwin's Exact Test

	Positive	Negative	Total
Yes	10	2	25
No	4	5	19
Total	28	16	44

$\chi^2 = 3.5$
 $P = 0.06$

Using the Fisher-Irwin Exact Test it was established that the differences between the two groups were not significant, consequently H_0 cannot be rejected. It may be suggested therefore, that where there had been a failure to communicate requirements, such an event did not affect the attitudes of those subjects towards the intervention. It is declared, however, that the differences approached significance. H_0 is therefore upheld with caution.

23 subjects indicated that the requirement for continuous use was acceptable.
14 subjects indicated that they were pleased that such a requirement was necessary (3 of these indicated that they were "delighted").
7 subjects indicated that they were disappointed that such a requirement was necessary (one of these indicated that he was "annoyed").

5.5.2.9 Test 5: The effect of treatment problems on attitudes

Data was available to ascertain whether less favourable attitudes were associated with problems declared by subjects.

Table 44: Subjects Reporting Problems with Devices

Experimental Group n = 10		Control Group n = 5	
Healed	Unresolved	Healed	Unresolved
7	3	1	4

Table 45: Severity of Problems

Mild	Bearable	Noticeable	Serious	Very Serious
13	1	0	1	0

Responding to the question of continuous use of devices:

- 8 declared that they considered the requirement to be acceptable.
- 5 declared that they were pleased that there was such a requirement.
- 1 declared that he was disappointed.
- 1 other was strongly opposed to the treatment and would not qualify his response.

A further hypothesis was generated. It was considered that the problems experienced by the subgroup, declared above, differentiated them from other subjects in terms of the attitudes they expressed towards the requirement for continuous use of orthoses.

H_0 *The attitudes declared by subjects who had experienced problems were not different to subjects who had not.*

Table 46: Comparing attitudes towards continuous use:
Subjects who had experienced problems vs. subjects who had not

Group	Delighted	Pleased	Acceptance	Disappointed	Annoyed	Total
A	0	5	8	1	0	14
B	3	6	15	5	1	30
Total	3	11	23	6	1	44

Data were collapsed to facilitate Fisher Irwin's Exact Test. Responses categorised as "Acceptance" were considered neutral and were not included in analysis.

Table 47: Attitudes towards continuous use: Fisher Irwin's Exact Test.

	Positive	Negative	Total
A	5	1	6
B	9	6	15
Total	14	7	21

$\chi^2 = 1.05$
 $P = 0.30$

It was found that the attitudes suggested by the subgroup were not significantly different to the remaining study sample, consequently H_0 cannot be rejected. It may be concluded therefore that the problems declared by the subjects did not affect their attitude toward the requirement that the orthoses should be worn continuously.

5.5.2.10 Tests 4 and 5: Discussion

From the findings relating to the requirement to wear the orthoses continuously, three points were evident.

1. Ulcer healing appears not to have been associated with subjects' understanding of intervention requirements.
2. Where subjects indicated that they had not realised that there would be a requirement to wear the devices continuously, the effect of communicating this requirement did not cause a negative response.
3. It was found that the attitudes, suggested by subjects who had experienced problems with the devices supplied, were not significantly different to those of the remaining study sample. This does suggest that the nature and severity of the problems that were encountered were not significant. It should be considered however that the perception of these problems was likely to be relative to other disadvantages experienced by the subjects. The magnitude of problems common to most subjects in the trial are likely to be such that an ill fitting orthosis is unlikely to be considered important. However, in terms of acceptability of treatment, the significance of such an observation may be salient.

Of the 44 subjects who responded to the question relating to the requirement for the continuous use of orthoses: 7 declared that they were disappointed (1 declared that he was annoyed), 23 suggested that they considered the requirement acceptable and 14 were pleased (of this number 3 were delighted). These findings suggest further evidence of a positive trend in attitudes towards the treatment. It is accepted that the effects of long term commitment may include changes in attitude, particularly amongst subjects for whom the orthoses are not efficacious.

5.5.2.11 Test 6: The relationship between participation in social activities, ulcer healing and attitudes to the intervention.

Subjects were asked whether there had been perceptible changes in their approach to participation in social activities in the twelve month period since treatment began. The dependent variables considered were social activities, documented by Rao (1992) and others (Littlewood and Lipsedge 1989), that have been identified as being adversely affected by deformity or disability secondary to leprosy.

The investigation sought to establish whether perceived changes in the subjects' approach to participation in social activities could be associated with ulcer healing and/or allocation to either the Control or Experimental Groups. A further aim was to consider the relationship between such changes and attitudes to the intervention. Hypotheses, related to these issues, were generated and tested respectively.

5.5.2.12 The association between ulcer healing and perceived changes in social activity participation.

H₀ Subjects with healed ulcers did not report changes that were different to those reported by subjects with unresolved ulcers.

Subjects were compared on six variables:

- | | | | |
|--------------------------------|------------------------------------|-----------------------|-------------|
| Travel | Marketing | Public Worship | Work |
| Eating in Public places | Attendance at Public Events | | |

For each activity of interest the respondents were requested to indicate whether their participation was:

- | | | | | |
|-------------------------|-----------------|---------------------|--------------|-------------------|
| Greatly Improved | Improved | No Different | Worse | Much Worse |
|-------------------------|-----------------|---------------------|--------------|-------------------|

Analysis

Data were collapsed to facilitate χ^2 test. Where expected occurrences were five or less Fisher's exact test was used. "Greatly improved" or "improved" were categorised as "Improvement". "No different", "worse" or "much worse" were categorised as "No improvement". No "much worse" responses were declared.

Table 48:

Changes in Social Activities: Healed Group n = 24 Unresolved Group 22

	Improvement		No Improvement		χ^2	p value
	Healed	Unresolved	Healed	Unresolved		
Travel	19	7	5	15* ²	10.47	0.001
Market	21	6	3	16* ³	17.17	<0.0001
Worship	21	12	3	9	5.27	0.02
Work	22	6	2* ¹	15* ⁴	18.9	<0.0001
Public Eating	12	9	12	13* ³	.38	0.5
Public Events	19	8	5	14* ³	8.67	0.003

*¹ 1 was worse
*² 4 were worse
*³ 1 was worse

*⁴ 2 were worse
*⁵ 3 were worse
*⁶ 3 were worse

5.5.2.13 **Changes in social activity participation comparing Experimental and Control groups**

An hypothesis suggesting that subjects in the Experimental Group would have reported greater changes in social activities than Control Group subjects was tested.

H_o Subjects in the Experimental Group did not report changes in social activities that were different to those reported by subjects in the Control Group.

Analysis

Table 49:

Changes in Social Activities: Experimental Group n = 22 Control Group 24

	Improved		Not Improved		χ^2	p value
	Experimental	Control	Experimental	Control		
Travel	14	13	8* ¹	11* ⁵	0.42	0.5
Market	17	10	5	14* ⁶	6.00	0.01
Worship	16	17	6	7	0.02	0.88
Work	15	13	7* ²	11* ⁸	.94	0.33
Public Eating	13	9	9* ³	15* ⁸	2.14	0.14
Public Events	17	10	5* ⁴	14* ⁹	6.00	0.01

Experimental Group

- *¹ 1 was worse
- *² 2 were worse
- *³ 1 was worse
- *⁴ 1 was worse

Control Group

- *⁵ 3 were worse
- *⁶ 1 was worse
- *⁷ 1 was worse
- *⁸ 2 were worse
- *⁹ 2 were worse

5.5.2.14 Test 6: Discussion

Clearly, beneficial changes in social activities were associated with ulcer resolution. Ulcer resolution has been associated with attitudes to the intervention. It could be inferred therefore that the intervention was indirectly associated with changes in social activity.

There are two possible explanations for the differences reported between the Experimental and Control Groups when compared on marketing and public events. The first consideration is that there were a greater number of subjects with healed ulcers in the Experimental Group (n = 22: 16 Healed 7 Unresolved) than in the Control Group (n = 24: 10 Healed 14 Unresolved) at the time of reporting. The second consideration relates to the period of intervention. Responses to the question related to perceived changes in the twelve months before January 1995. Whereas the Control Group had been supplied with devices in March 1994 the Experimental Group had been supplied with devices in August 1993. The twelve month period of interest, therefore, included ten months of treatment for the Control group. The Experimental Group, however, could relate to a twelve month period within a span of eighteen months wherein they had been exposed to the intervention. Related to this factor is that a significant number of subjects in the Experimental group had presented with healed ulcers before the intervention was extended to Control Group subjects.

Markets

Of the variables considered, going to markets and attendance at public events are situations wherein the subjects would be most exposed to public view. Visiting a market to buy food is an essential function conducted at least once a week. A perceived freedom from public glare is likely to bring about an early realisation of the importance of healing.

Public Events

A feature of Indian culture are the numerous festivals and social activities which create opportunities for the development of cultural identity. The exclusion from such

functions may be a salient factor that perpetuates the erosion of self esteem and sense of identity. A perceived acceptance at such events is likely to be profound.

Eating in public

Of the variables considered, "eating in public" was least likely to have been affected by ulcer healing. Social eating is a popular feature of Indian culture. The satellite colonies around Kondhawa not infrequently organise events where large gatherings of similarly impaired people gather for celebrations. In these sheltered situations ulceration and deformity are not considered barriers. Patronising restaurants is unlikely to be a common experience as the subjects are generally considered to comprise a low income group.

Work

Similarly, most of the subjects are employed in the rehabilitation enterprises organised by the Poona District Leprosy Committee (See section 2.1.1.). Stigma is not a feature of daily experience in these work units. The significant improvement recorded between the "healed" and "unhealed" groups may reflect a perceived (or real) functional improvement.

Travel

The form of public transport most commonly used by the subjects is likely to be a timetabled municipal bus that runs, on a frequent basis, between Kondhawa and Pune. This service is locally known as "the hospital bus" and is renowned for carrying "leprosy patients". Passengers who routinely use this service do not generally appear to discriminate against the leprosy impaired. This is possibly an effect of familiarity. As a consequence the subjects in this study were unlikely to benefit as much from reduced exposure in these buses as they would be when exposed to a more general public. The significant difference between healed and unhealed groups may indicate a greater freedom to extend travel activities and to use forms of transport that may otherwise have been considered hostile environments.

Worship

Valid comment on the results relating to differences in "worship" require more information than was available. Worship is an intimate and profoundly subjective experience. For some individuals worship will be a fundamental feature of life whilst for others it will be meaningless. Where subjects indicated that "worship" was "no different" such a response may indicate that worship was irrelevant.

There are further variables to be considered. The acceptance of leprosy impaired at Hindu temples will depend on the locality of the temple, the deity worshipped and the rituals observed. There is a temple dedicated to Ganesh at Kondhawa. Presence of subjects at this venue is unlikely to be problematic. However intra-subject devotion to individual deities is certain to be varied as individual preference is encouraged. There is a sub group of Islamic devotees for whom the experience of worship is also likely to depend on the locality of a preferred mosque and ritualistic demands.

There are also a number of Christian subjects. These individuals meet routinely and have established a strong identity. All the members of this group present with leprosy impairment or are intimately associated with others who do. The presence of ulceration is unlikely to affect the worship of this group.

5.6 GENERAL DISCUSSION

5.6.1 METHODOLOGICAL ISSUES AFFECTING THE DESIGN AND IMPLEMENTATION OF THE INTERVIEW SCHEDULE

Proctor (1993) cautioned that underlying attitudes are not the sole determinants of verbal (or non-verbal) behaviour. Brenner (1985) emphasised his contention that the interviewer and, more precisely, interview technique, are the most crucial components of social situational circumstances that affect interview responses. Fielding (1993) acknowledged that there is a considerable weight of literature which recognises interviewer effects on response. Concerning the demands of reliability and validity, it is recognised that there are potential problems when data are gathered by interview. However the procedure constituted the only valid method whereby access could be gained to the type of information required for this aspect of the study. An ethnographic study, or content analysis of an unstructured schedule, might have yielded a more definitive insight but these methods were not practicable. Every attention was paid to identifying and limiting potential sources of bias. The complexities of human interaction, however, must have had an effect on the question and answer transaction between participants in the interview process.

Dijkstra *et al.* (1985) conducted a study of the response effect of interviewer's style of behaviour. Interviewers were subjected to training in the "formal style" and "socio-emotional" style. The former recommends that the interviewer should avoid person oriented actions and not deviate from strictly task oriented actions. By creating the same conditions for each respondent, stimulus conditions will be standardised. This "positivist" perspective reduces the possibility of measurement bias. The socio-emotional style endorses a supportive, sympathetic understanding technique. An environment approximating that in which routine social conversation is enacted is developed to allow the respondent to develop a relationship with the interviewer. The rationale supporting the socio-emotional style is that the approach is a prerequisite for responses to questions relating to sensitive topics. By analysing the speech acts of interviewers and respondents, Dijkstra *et al.* (1985) found that more personal

information was given to socio-emotional interviewers but most of that information was irrelevant. The amount of adequate information gathered by socio-emotional interviewers was the same as that gathered by formal interviewers. Of greater significance, however was the general observation that in 40% of question and answer sequences the interviewers acted inadequately, leading to a criticism that such behaviour may result in biased information. These issues were emphasised when training the interviewer.

5.6.1.1. Respondent effects.

Subject motivation to respond effectively is a difficulty that is most likely to confound measurement adequacy in a survey. The interviewer cannot intervene in any manner that may reflect an explicit interviewer effect on the subject. The integrity of the interview is dependent on the motivation of the subject to co-operate with the interviewer (Brenner 1985).

Respondent anxiety has been reported as imposing a considerable threat to reporting integrity. Acute anxiety may arise as an immediate response to question threat, thereby heightening the effects imposed by a steady level of chronic anxiety. Questions relating to deviant or contranormative behaviour, or questions that threaten to expose views on socially sensitive topics are likely to cause anxiety. Bradburn and Sudman (1979b) reasoned that questions relating to these issues involved social definitions of desirable behaviour, a consequence is that respondents will be likely to under-report to avoid deviant labelling. Conversely, over-reporting may also be a problem where questions present an opportunity to display highly desirable social characteristics (the social desirability effect). Consequently, there is a dilemma for the investigator to resolve: the responses recorded will reflect either the integrity of the subject as a respondent, or the desire of the respondent to present a positive self image. These issues have been subjected to two approaches of investigation. One approach was to examine the method of administration, thereby identifying features likely to arouse threat. A second approach was to study trait and state anxiety as independent variables effecting self esteem (these issues are reviewed definitively by

Bradburn and Sudman [1979b]). The practical implications arising from their study suggest important considerations for question structure. It was established that a biased response may be reported as an effect of perceived question threat. However, this effect was not as great as the effects of question structure.

5.6.1.2 Question structure and schedule design

Symbolic interactionism¹⁹ suggests that questions, with associations of contranormative behaviour, should not be presented in such a manner that the respondent is confronted by a dichotomous or other closed question response. Not only do such questions confront the respondent with a challenge to self esteem, but a further threat is imposed by enforcing a demand to choose from limited alternatives. Those who perceive the questioning to be threatening select a response that screens them from subsequent questioning. By denying involvement in contranormative behaviour the respondent resolves the conflict between response integrity and positive self image but leaves the investigator with an inadequate response. Strategies to cope with this dilemma require consideration where sensitive questioning is to be implemented. However, where responses to questions of a less threatening nature are required, stimulus conditions may be standardised thereby reducing the possibility of measurement bias. Dijkstra *et al.* (1985) suggested that, where possible, a mixed approach (formal and socio-emotional) should be adopted as it may elicit an overall response demonstrating greater validity. This advice affected the design of the schedule used for this study.

19. In a symbolic-interactionist perspective the interview will be defined as a social event based on mutual participant observation (Silverman 1989). As such the context of the interview plays a fundamental role in the nature of responses. The context should therefore be considered a resource to be exploited to gain quality data through developing a mutual understanding between participants. Using a system of open ended questions, with suitable prompts and probes, the respondents are encouraged to participate in a manner which is meaningful to him/herself. As a consequence, the respondent may be able to present considerations that would otherwise have been missed if a more positivist perspective is respected (Fielding 1993).

5.6.1.3 **The advantages and disadvantages of quantitative data analysis**

It was suggested above that a qualitative approach to the collection of attitudinal data is most likely to yield a clearer indication of respondents' perspective. The reasoning applied to this view is that quantitative analysis is too mechanical. It requires the equal weighting of categorised data which is not a reflection of human interaction. When a quantitative approach is adopted, ambiguity is not tolerated. Such an effect may be a desirable scientific goal, but the cost of such rigour is the loss of the intrinsic richness of experience.

The major criticism of qualitative analysis however is that it has not demonstrated repeatability. The reliability of qualitative findings may, therefore, be questionable. Mostyn (1985) suggests reasons for this negative attribute. These include difficulty in the precise analysis of data and circularity (the researcher being influenced by the hypothesis). She continues by reflecting the view of Krippendorff who suggested three reasons for lack of reliability:

1. Qualitative data is multi-faceted and the analysis may reflect the perspective of the analyst rather than the meaning intended by the subject.
2. Data is not obtained independently of the measuring instrument, consequently contamination effects are inevitable.
3. Duplication of effort is essential to test reliability. This is, in most instances, an unrealistic requirement.

Berelson (cited by Mostyn) advised that a quantitative approach should be reserved for studies where:

1. A high degree of precision is required.
2. Impressionism may be subject to bias.
3. Where content data will be statistically linked to numerical data.

A high degree of precision was not considered a feasible objective of this aspect of the study as attitude is a highly subjective concept. However, it was accepted that impressionistic representation may be biased by circularity and ethnographic misinterpretation. It was considered that the latter issue was potentially a greater

source of bias.

5.6.1.4 Cross Cultural Considerations for Schedule Design

Bradburn and Sudman (1979a) found that questions using wording chosen by respondents did not elicit higher reporting levels for threatening questions. The latter finding appears counter-intuitive and indeed Bradburn and Sudman do emphasise that consistent results support the wisdom of familiar wording. Where semantic analysis is sought, idiom should be a fundamental consideration. It is suggested that this issue is particularly relevant in the context of this study where it is accepted that the majority of subjects were illiterate. It was essential therefore that interactions were conducted idiomatically, as subjects were expected to offer verbal responses. The interpretation of interview response was a further issue in this study. Difficulties in establishing equivalence of meaning in translation were exacerbated since much of the material to be analysed was attitudinal.

Concerning response validity, other researchers associated with interview procedure in developing countries have identified interviewer bias as a major source of system error (Kroeger 1983, Ross and Vaughn 1986). Re-interview, as a check on repeatability has been shown to produce variable results. Ross and Vaughn (1986) suggested that discrepancies may be attributed to factors including resentment due to further intrusion, perceived criticism of earlier responses, and interviewer bias. They observed that these factors were particularly relevant in developing countries. The criteria for a suitable interviewer, given the sociocultural context of the study, were characteristics of the interviewer commissioned to conduct the survey. It is suggested, therefore, that the responses recorded were not subject to interviewer bias.

Following the recommendations of Ross and Vaughn the internal consistency of the of completed schedules was checked every evening. This facilitated daily feedback to the interviewer. Where grossly unexpected or apparently illogical results were identified the interviewer was requested to clarify the results with the respondents.

Events of this nature occurred twice The interviewer was accompanied by an independent observer on a number of occasions to check on the validity of translation and recording procedure.

Accepting the limitations suggested in the preceding considerations, the author was confident that the responses that were recorded are reliable and that the inferences drawn from them are a valid reflection of the attitudes of the trial subjects.

5.6.2 THE FOOT HEALTH SCHEDULE

This aspect of the survey generated data that described the opinions and behaviour of the study sample related to the practice of self foot care. It was found that subjects with ulceration did not report self care practice that was significantly different from subjects without ulceration. This finding supported the efficacy of the intervention in that it demonstrated that behaviour bias did not confound the results recorded. It was, however, the aspect of the schedule that focused on the behaviour/opinion association that was more pertinent to developing an impression of attitudes.

It had been considered that scores demonstrating good practice would correlate positively with scores for opinions of foot care recommendations. In retrospect, it was perhaps an ethnocentric assumption that subjects would not comply with recommendations perceived to be unimportant. It was found that a hypothesis generated by such an assumption found scant support in the results. It is suggested, however, that the results indicate the relevance of causal and recovery beliefs and the principal agents of social control. These factors did appear to influence the behaviour of the leprosy impaired in this study.

5.6.2.1 Motivation

That there should be a more appropriate effort to motivate those who have been chronically impaired for an extensive period was an opinion voiced by Srinivasan (1991). It is the author's contention that until the problem of stigma can be overcome, few advances can be made. One objective of this discussion is to clarify this opinion.

In the preface to the ILEP Guidelines for Leprosy Control Programmes (1993), Dr Felton Ross suggested that impairment control is a practicable objective. It is, however, dependent on the "close co-operation between well-informed patients and well-trained staff." The principal factor affecting impairment control is considered to be sound pragmatic advice. Clearly, pragmatism in this context must include the sociocultural context in which the advice is to be delivered. Western models of

effective communication may not be valid without some adjustment to satisfy cultural differences. The findings of this aspect of the study suggest that a widening in the perception of what is understood by the terms "well-informed patients and well-trained staff" is necessary if effective impairment control is to be realised.

The study population have been exposed to high levels of health education at Dr Bandorawalla Leprosy Hospital. The institution strongly advocates self care and the study population are widely exposed to a variety of visual prompts to encourage responsible foot care activities. In this respect, the study population are probably better "resourced" than the general population of leprosy impaired subjects. Although this approach does appear to have had a measure of success, questions that arise are: has it addressed the fundamental problem of exclusion? If patients cannot perceive any release from the figurative bondage of stigma, is it conceivable that greater motivation can be expected? It may be that by allowing patients the dignity of active participation in decision making a reintroduction to the mainstream of life might be conceived. Such an adjustment may facilitate greater levels of motivation.

The WHO (1984) defined health education as an aspect of health care concerned with the promotion of health behaviour. An objective of health education, therefore, is that it should broaden perspectives and enable patients to participate in choosing actions that will improve their health. Participation in health education implies a positive interaction between the provider and receiver. This effect may be generated through a variety of methods which have been demonstrated as changing health behaviour related to diverse diseases.

By way of example, in recent years recourse has been made to social learning theory to develop reinforcement techniques to enhance adherence to instruction (Morgan and Little 1988, Leslie and Schuster 1991). Contingency contracting²⁰ has demonstrated the validity of operant conditioning theory. The basic principle of operant conditioning is the premise that voluntary behaviour is dependent on

20. Contingency contracting is an overtly rewarding approach. Patients are encouraged to commit themselves to desirable actions by entering into written contracts assuring them of material rewards for maintaining desirable behaviour.

perceived consequences. By positive reinforcement of desirable behaviour the subject is conditioned to increase the frequency of such behaviour. Desirable behaviour without reinforcement has been found to be less sustainable.

5.6.2.2 The Effects Of Stigma

Indian leprosy sufferers have been discriminated against and marginalised. Stripped of self esteem and denied recognition within the corporate nature of mainstream Indian life many become socially disorientated. The sufferer is constrained to be associated with other members of an "ugly" subgroup. With the passing of time the sufferer accepts his role, "becomes" repugnant and accepts "untouchability" (Berreman 1984). This scenario is broadly accepted but the question as to whom is responsible for role orientation is debateable. Assuming Parson's theory,²¹ it is the "doctor", acting primarily as an agent of social control, who influences the extent to which a disease carries the potential to stigmatise in society.

Volinn (1983) considered the work of Papper (1970) who identified characteristics that frustrated the physician's expertise and challenged their role to cure the sick and reintegrate them into society. Volinn summarised three of Papper's broad criteria of characteristics with the potential to stigmatise. They include:

1. Social characteristics, i.e. old age, race, religion, ignorance and uncleanness.
2. Patient behaviour (particularly rejection of medical authority).
3. Chronic and/or malignant conditions that do not respond to medical treatment.

She then continued to suggest that many of the characteristics apply to both leprosy and alcoholism, thereby supporting her claim that the conditions are similar in their social impact²². Implicit in her perspective is the validity of the Parsonian theory of sick role. As suggested earlier this supposition may need to be approached with caution. In India, it is perhaps not the physician who is the primary agent of social

21 Parson suggested that doctors are ascribed authority to construct the images that the diseased present to society. It is the doctor who legitimises the "sick role". Parson (1951)

22 Volinn's paper is useful because it does permit a perspective on leprosy shared by Western experience: i.e. we are familiar with the social problem of alcoholism. However, I feel that the fundamental difference between Western social attitudes toward alcoholism and attitudes toward leprosy in endemic countries is that our attitudes towards alcoholism are not affected by fear of contagion.

control. It may be that a historical perspective would be more applicable as it is possible that Hindu teaching is perhaps still the primary agent of social control. This effect is suggested in the study of Dalal and Singh (1992). The results of their study of causal and recovery health beliefs amongst Indian tuberculosis sufferers indicated that a reluctance to report traditional or cosmic beliefs may have been a source of bias.

Clearly, that doctors in India are recognised as authority figures is evident in Dalal's study, and as such they significantly influence the shaping of concepts of health and disease for the public. Where the doctor's perspective is influenced by the factors reported by Papper, it is logical to surmise that the image perpetuated amongst his/her society will reflect those influences.

If Goffman (1961) was correct and stigmatised individuals do not define themselves as different from anyone else, then it is not the "leper" who distances himself from society. It is society, fuelled by ignorance, or intolerance (as illustrated by Papper) that imposes the divide of stigmatization. However, after considering Valencia's argument the author was persuaded that the reality, is more complex. It is not predominantly a question of other agents of control creating the role of "the leper". A question arising from the studies of Valencia (1988) and Waxler (1981) is provocative: i.e. are we afraid to lay any responsibility for his isolation on the patient himself? An implication of Goffman's theory is that the perception differential is an artefact manufactured by others and not by the patient. Valencia suggests that the patient is equally responsible for reinforcing the negative attitudes s/he experiences. She opines that there is an accepted erosion of self esteem preventing patients from asserting themselves in family and community affairs thereby creating "self-stigma". It may be that "self stigma" is as great an actor in the drama of leprosy as the bacillus is:

"Self stigma is also disease producing: although it may not produce a bacterium or micro-organism, it will produce a pathogen of negative social reactions which will, in the end, inhibit an effective delivery system of services by control programs."
(Valencia 1988 p 849.)

The wilful consent to social restriction and passive acquiescence to persecution is an expression of retreat from positions where sufferers might assume more significant roles in their communities. Due to this quiet acquiescence to social isolation, the leprosy sufferer ceases to be a significant person in the community. If such persons are aware that the disease will persist and that therapy may not control impairment or deformity (as indeed it may not) then a lowered self image seems inevitable. A primary consideration of treatment, therefore, should not only be the application of therapeutic prescription, but an emphasis on empowering the patient to enhance his own self image.

Using Goffman's terminology stigma should be considered a "language of relationship". This relationship, existing between the patient and community, is complex. It is based not only on the manner in which the patient and community cope with the patient's deformity, but also on the patient's projection of his own sense of self worth. It follows that if the patient is able to view his deformity objectively and avoids behaviour that invites attention to his abnormality he is likely to be rewarded by respect for his courage. Instead of being denigrated he may, as a consequence, be valued.

In conclusion, it is the author's contention that stigma is a major factor in the erosion of motivation for both the sufferer of leprosy and the care provider. Socio-cultural factors in Indian society may have denied the sufferer a voice and acting within the norms of his society the sufferer has passively acquiesced. The effect of such acquiescence is not broadly recognised as being pathological and, consequently, the low motivation of individuals is perceived as illogical and irresponsible. The cynicism that has developed as a consequence perpetuates a negative attitude toward the sufferer which exacerbates the communication breakdown between carer and receiver.

5.6.2.3 Causal and recovery beliefs

A study alluded to earlier, conducted by Dalal and Singh is particularly pertinent due to its cultural relevance (Dalal and Singh 1992). They studied the linkage between perceived control and psychological adjustment with associated causal and recovery beliefs. The population they studied was a group of Indian patients suffering chronic tuberculosis. They discussed the implications of their findings which suggested that subjects attributed disease to cosmic factors (God's will and Karma) but recovery from disease primarily to health professionals. An important conclusion from their findings was that recovery beliefs have a closer relationship with perceived control than causal beliefs. This may be because Karma is believed to explain why events have transpired. Future events are thought to be dependent primarily on Dharma and the influence of several other factors. In the study conducted by Dalal and Singh, "doctors" were considered to be one such significant factor.

Karma may moderate the effect of causal beliefs as it offers an explanation for disease. It is also associated with situational acceptance and has an association with self blame. Significantly, self blame has been associated with a high sense of control (Bulman and Wortman 1977). Dalal and Singh did find that other external causal factors (the carelessness of others and family conditions) were associated with poor adjustment, probably because of their implications regarding social support mechanisms. However the weight of their evidence does suggest that recovery beliefs were a more important influence on perceived control.

An important finding of Dalal and Singh's study was that perceived control over disease was correlated with psychological adjustment. Control, in their study, was related to recovery beliefs. Attitude to treatment in similar populations, therefore, may be influenced by recovery beliefs. If the subject attributes recovery to cosmic factors (s)he is unlikely to have a high opinion of measures perceived to be independent of such factors. If the subjects' recovery beliefs are associated with an alternative powerful external locus of control (eg. doctors: as found by Dalal and Singh) (s)he is unlikely to consider self care as meritorious. It would appear logical

therefore that by promoting self esteem and internalising the locus of control, "self" care should be more effective. Afleck *et al.* (cited by Dalal and Singh 1992) found that a higher level of personal control over health care was associated with positive attitudes and psychological adjustment. Negative mood was found to be associated with control perceived to be exerted by health professionals.

The problem of ethnocentricity must be recognised to be avoided. The concept of "self" is not as powerful in India as it is in the West. Karitkayan and Chaturvedi (1992) conducted a study of Indian agricultural workers affected by leprosy. The dynamic that enabled these workers to respond to the constraint to continue working was that they might avoid dependence on family members thereby minimising loss of dignity. The significance of familial identity is profound. It even extends to affect industrial and commercial employment arrangements where the relationship between the employee and the company is developed on the basis that it is a lifetime relationship. For many an effect of modernisation and the erosion of traditional family structure is that the company becomes a surrogate family. In this manner, the security previously assured as a role of the traditional family is provided by the company. Institutions with which individuals may bond can become as significant.

When considering the needs of the individual, (s)he should not be assessed out of the context of her/his familial role. It is the corporate need of the body of the family that is significant rather than the individual in isolation.

5.6.3. THE ATTITUDE PROFILE

The opinions of the respondents suggested that subjects held the intervention in high regard. This was established, initially, by considering the recommendation that the intervention should be extended to others. A suggestion, therefore, that the subjects' attitudes toward the intervention was positive has face validity. There was a possibility, however, that opinions were influenced by other factors. The attitudes may more closely have been associated with perceived care which, although related, is an extraneous variable.

Modelled on the practice of nursing, Carnevali and Patrick (1979) explained the reorientation of professional perspectives from that of a "curing" profession to that of a "caring" profession. Whilst "cure" probably remains the focus of doctors it is "care" that is the major focus of nurses and some other paramedical and health care disciplines. The positive values, encouraged in a provider/receiver relationship in a health care environment, effectively promotes the patient's sense of worth and human dignity. Implicit in the definition of treatment is that it is a mode of caring behaviour. As such "treatment" implies elements of concern and goodwill. Where it is not perceived as serving the self interest of the provider, and is considered essentially altruistic, the act rather than the form of treatment may have significant implications for the psychosomatic well being of the patient. The significance of this effect may be heightened in the context of this study where individuals may have perceived an element of social desirability in being subjects of the concern of a foreign "doctor".

This effect has been documented. "The wise" is a term used by Goffman (1961) to describe individuals who do not demonstrate any stigmatising characteristics, but who through empathy and intimate knowledge are so closely identified with the stigmatised that they become courtesy members of the stigmatised group. The "care" model suggested by Carnevali and Patrick (1979) predisposes carers to accept the implications of chronic disease. Effectively trained carers are facilitated to accept the "entire" patient without exception to his recurrent problems and potentially repulsive sequelae. Volinn (1983) studied the effects of nursing as a destigmatising agent. She

found that nurses in a Skid Row drop-in centre acted as advocates of the group they served and as such demonstrated the concept of "the wise". Their professional expertise was combined with an empathic concern. They were protective of their patients, recognised their dignity and emphasised the individuality of those in their care. There were expressions of mutual trust which was considered evidence of destigmatisation.

It was considered earlier that stigma may be a significant factor affecting compliance. It is possible that this project demonstrates an effect of destigmatisation. The ready compliance and apparent enthusiasm for the intervention may be an effect of perceived care. It may be that the effects of the intervention cannot be considered independently of the effects of perceived concern administered either by the author or the technician.

An attempt was pursued to establish whether there was evidence of "provider bias" (i.e., whether subjects supplied with orthoses by the author, responded differently from subjects supplied with orthoses by the technician). A hypothesis based on this consideration was not supported.

Further investigation sought to establish whether respondents who had expected healing to have been quicker responded differently from respondents who had not. There was no significant difference between the dichotomous responses of both groups but their attitudinal responses were different. It was demonstrated that 58.7% of subjects did not expect faster healing than that which they had experienced. These subjects ($n = 27$) were more positive in their responses to the question. However, of those subjects who had expected faster healing ($n = 19$) only five subjects expressed disappointment at the outcome. Seven subjects, with unresolved ulcers at the time of interview, expressed that they had not expected quicker healing. However, when asked to qualify their responses they declared that they were "pleased" or "delighted" with the healing rate they had experienced. This was considered an important sub group. There was scant evidence to support the suggestion that the responses of this sub group were affected by confounded expectation, as their ulcers had not healed.

Their indication of positive satisfaction was considered to be attributable to the intervention.

It is possible that previous treatment attempts had failed (or recurrence had caused the subjects to perceive that treatment had failed) leaving subjects relatively cynical about further methods. A positive outcome may, in such circumstances elicit a response relative to the unexpected nature of the event. Cynicism may be a mechanism through which such subjects learn to cope with illness.

The manner in which individuals adjust to chronic disease is a topic that continues to stimulate much interest. It appears that causal beliefs are fundamentally important in explaining why some individuals maintain control over their illness whilst others relinquish control to health providers. Control over disease has important implications for the psychological well being of the patient. Dalal and Singh (1992) cite the findings of Nicassio *et al.* to demonstrate the point that patients who considered themselves to have control over the illness were less depressed than patients who did not.

In the West, patients generally appear to seek explanations for their illness from medical practitioners who base their theories on scientific empiricism. Causal beliefs in India are still largely structured by traditional healers who focus their explanations on cosmic factors (Durkheim 1976, Kapur 1979). It was suggested earlier that belief in Karma may allow a smoother adjustment to disease because disease is not attributed to God but to the misdemeanours of the patient. Because they do not perceive themselves to be the victims of arbitrary punishment, an element of control is perceived which enables the patient to cope with their circumstances. Karma does however necessitate situational acceptance, consequently a fatalistic resignation to circumstance is implicit in adjustment. Positive health events are not generally expected, consequently, when positive changes are not apparent there is a limited effect on morale, conversely, when an unexpected positive event occurs the effect may be an exaggerated sense of zeal.

5.6.3.1 The association between changes in perceived improvements in social activities and attitudes to the intervention

Whilst developing a profile of Indian culture to provide a context for the implications of this study certain salient factors emerged. With modernisation's obligatory trends toward industrialisation and urbanisation, India's social equilibrium is being disturbed. An effect is that there is a drift away from characteristic traditional Indian Society (Liddle and Joshi 1986, Ghadially 1988, Littlewood and Lipsedge 1989). It seems apparent, however, that the modification of traditional structural norms and values has not constituted an abandonment of India's cultural infrastructure. The inculcation of traditional cultural norms continues to affect the developing industrial ethos of India. An effect is that even though profit making has become an important principle of economic rationality, communal solidarity is still considered to be of primary importance.

The social events of village life constitute fundamental elements contributing to the cohesion of group solidarity. Communal development is an essential feature of Indian social structure. A consequence of "internal exile" therefore is that it excludes the individual from group identity thereby effectively assigning him/her to a "non person" role. Rao (1992) has emphasised the significance of this observation by demonstrating that 84.9% of deformed leprosy patients do not take part in village social events. It is his opinion that deformity and/or ulceration is a serious deterrent to normal life debarring those who display disfigurement from social acceptability.

To be denied a role within the socio-cultural matrix of Indian society, is to be denied a basic human opportunity to aspire to dignity and purpose. Such is the power of cultural identity that physical discomfort will be borne where it is the cost of recognition. These factors contribute to the gravitation of the leprosy impaired to colonies of similarly disadvantaged sufferers. In these relatively sheltered environments strenuous efforts are made to recreate and rebuild communities that in all respects mirror other villages. They differ only in their isolation.

There are other features of the study population that does make it atypical. The majority are employed in the diverse industrial units registered under the title, *Dr. Minoo Mehta Apangoddhar Sahakari Audyogic Utpadak Sanstha Maryadit* (Mehta 1992). As these are rehabilitation units for the disabled, employees enjoy the security of sheltered employment.

These enterprises are situated in the Kondhawa and Bhosari districts of Pune where some subjects have established homes in the community. Others live in colonies that have developed in proximity to Dr. Bandorawalla Leprosy Hospital and the Kondhawa enterprises. Individuals classified as "others" in this study include hawkers, mechanics, retired individuals, a student, a domestic servant, a watchman and a liquor merchant. All of these subjects live in local communities in the Pune district.

Responding to the question relating to improvements at work, 88% of the "Healed" group indicated improved activity. It is probable that this result reflects a functional improvement rather than a psycho-social improvement. It is suggested however that the other results may reflect changes that have permitted "Healed" subjects to integrate more successfully into mainstream activities away from the colonies in which they live. The reasoning supporting this suggestion is that there is no significant difference in the housing situations of either group. Many live in the colonies around Kondhawa where the majority of inhabitants are associated with leprosy and there is no stigma associated with ulceration or deformity. Subjects with unresolved ulcers are unlikely to be disadvantaged by prejudice in these locations, similarly subjects with healed ulcers are unlikely to perceive greater acceptance.

Responding to the question of "eating in public" 52% of the "Healed" group indicated improvement. However, 49% of the "unresolved" group also indicated improvement. This result suggests that healing did not advantage subjects significantly concerning eating in public. It was suggested earlier that eating in public may not have been a favoured social activity of the sample in general. However the result is given further consideration here. In his study Rao (1992) recorded that 60.0% of non-deformed cases did partake of food in public places but only 23.8 % of deformed cases did

likewise. He did not attempt to explain this finding. Further in his thesis, where the perceptions of non-diseased subjects was discussed, it was reported that it was unacceptable to the population for individuals with mutilated or bandaged hands or feet to eat in public. It was also recorded that hotels, in the district where Rao's study took place, refused entry to leprosy patients²³. It is perhaps because it is customary to eat from the fingers that public eating is particularly difficult for those for whom leprosy has caused hand deformities. If hand deformity is a significant barrier to admission to eating establishments (perceived or overt), it is perhaps unlikely that by addressing plantar ulceration an improvement would be effected.

5.6.3.2 A summary of the effects of the intervention on the selected social variables

It was demonstrated that changes in social activities were associated with ulcer resolution. Ulcer resolution has been associated with attitudes to the intervention. It could be inferred therefore that the intervention was indirectly associated with positive changes in the subjects' approach to social activity. .

Greater confidence to participate in the activities referred to may be a powerful indicator of the effectiveness of the orthotic intervention. Reference to the Delphi investigation on disability prevention issues demonstrated that although there are potentially dire functional consequences of the disease, it is the psycho-social sequelae that are considered most significant. This view is validated by extensive references to the issue in the literature.

5.6.3.3 The validity of the assumption that the attitudes inferred were associated with the intervention

Three questions were designed for the purpose of establishing the validity of the assumption that the attitudes inferred, from the interview schedule, were associated

²³ In the company of leprosy deformed subjects, I have patronised many and diverse establishments where food is prepared and sold and have not been aware of overt discrimination. It may have been that these individuals would have been subject to discrimination had they not been in my company.

with the intervention and not extraneous variables.

Potentially confounding variables were identified as being:

Attribution of effects to cosmic or other external sources.

Perceived social desirability of privileged status.

Significant life events.

5.6.3.4 Attribution of effects to cosmic or other external sources

The studies of Berreman (1984), Dalal and Singh (1992) and Rao (1992) have indicated the effects of belief systems on the orientation and attitudes of leprosy sufferers. It was attempted to ascertain an impression of such factors and the influence they may have exerted on subjects' attitudes. The question, however, met with confused responses and was considered an unreliable indicator. Consequently the responses were not analysed. The potential for these effects to confound the inferences drawn cannot, therefore, be discounted.

5.6.3.5 Perceived social desirability of privileged status

The rationale for including Question 5 was to ascertain whether attitude may have been biased by factors including personal loyalties or perceived favouritism. Although consideration of appropriate probes was made these failed to elicit satisfactory responses.

Most subjects were unwilling to commit themselves to an answer. These questions did require higher intellectual powers than previous questions, for which a more direct response was sufficient. A possible explanation, therefore is that the questions were too demanding for the average intellect of the sample. Alternatively, it may be that there was a perceived threat inherent in the question (the question may have been construed as veiled criticism). By considering that there may have been an element of personal responsibility for the cause of a disorder, chronically ill subjects in a similar population were found to have been challenged by a perceived requirement to accept control for their own care (Dalal and Singh 1992). It is possible that such a challenge

was generally unacceptable in the study sample. A further possibility is that the interviewer did not communicate the question, or prompts, adequately.

This question was consistently met with unsatisfactory and confused responses. Consequently these responses were also considered unreliable and were not included in the analysis. There remains a possibility, therefore, that because these subjects perceived an element of selection, their morale may have been elevated resulting in a positive effect on attitudes.

5.6.3.6 Significant life events

Psychological stressors including situations involving trauma, conflict or change have been associated with physical, psychological and behavioural reactions. Although it has been demonstrated that traumatic events are more likely to be associated with stress reactions (Mueller *et al.* 1977, Suls and Mullen 1981) even desirable events can be stressors if they require adaptation. Contributions by Lazarus and Launier (1978) helped develop current understanding regarding the manner in which psychological variables effect the impact of stressors. They, amongst others, have developed the pioneering work by Selye (General Adaptation Syndrome) to develop psychobiological models that emphasise the interaction of psychological and biological variables in regulating, and producing stress responses. It is broadly agreed that where an event is considered an uncontrollable threat, rather than a challenge, a far greater negative psychobiological impact may be the response. The potential implications for ulcer resolution are that physiological (particularly adaptations of the immune system) and behavioural responses to negative events may impede healing.

The Holmes and Rahe Social Readjustment Rating Scale (SRRS) rates stressors in terms of Life Change Units (LCU's) (Holmes and Rahe 1967). These reflect the amount of change and relative demand for adjustment that common stressors stimulate. However, LCU values may give a misguided impression as they do not consider the effects of stress mediators (social support systems and variations in individual coping skills). A more significant consideration in the context of this study

is that the SRRS is not a valid representation of the cultural norms and values of Indian society generally, and of Leprosy as a subculture in particular. However, it is suggested that the underlying principles of stress and reaction are applicable. Furthermore the general principle of impairment, relative to the number or extent of stressors experienced, is valid for the study population. Consequently, an impression of the independent effects of major life events on physical, behavioural (ulcer healing) and psychological (attitude) variables may contribute to the assessment of the effectiveness of the treatment.

In the absence of a suitable model, the concept of "significant life events" was developed from considerations drawn from the study of Indian culture and the effects of leprosy in India. This question did not present any difficulties to respondents but only 25 subjects could identify events that they had experienced within the experimental period. It was demonstrated that amongst these individuals ulcer status was not associated with significant life events.

Because responses were dominated by declarations of favourable events, it was considered that the attitudes to the orthotic intervention, declared by subjects reporting positive life events, may have been affected by raised morale attributable to the event experienced. This hypothesis was tested but could not be supported. Consequently it was concluded that attitudes were not affected by psychological response to stressors.

Issues arising from this discussion are considered in the conclusion to the study.

CHAPTER 6

THE APPROPRIATENESS OF ORTHOTIC TREATMENT FOR PLANTAR ULCERATION IN LEPROSY

6.1. INTRODUCTION

The parameters by which "appropriateness" may be gauged in the Indian context are sociologically and culturally specific. A consensus on indicators of "appropriate" impairment control measures in India was sought. This aspect of the investigation aims to discuss the findings of the study with reference to authoritative opinions on relevant impairment control issues.

This chapter will address the following:

1. The Indian infrastructure for the treatment of leprosy and its sequelae. (The relevance of issues presented in this chapter should also be considered in the wider cultural context discussed in Chapter 5 section 5.1.)
2. The Delphi Method of consensus reporting.
3. The execution of a Delphi investigation.
4. Discussion on the appropriateness of the intervention, based on criteria collected by the Delphi investigation.

6.1.1 THE INDIAN INFRASTRUCTURE FOR LEPROSY ERADICATION AND IMPAIRMENT CONTROL

With the establishment of the Indian Council of the British Empire Leprosy Relief Association in 1925 an infrastructure for the co-ordination of Leprosy field work began to emerge. Information relating to the efforts of voluntary organisations was collated with the effect that in 1937 it could be reported that 8,000 patients were being treated in 32 institutions. The work was almost exclusively run by The Mission To Lepers.

National awareness of the problem was promoted by no less a figure than Mahatma Gandhi who sought to mobilise the conscience of his countrymen. His resolve was to free India from the physical, social and spiritual oppression of leprosy. It may be speculated that an upsurge in National interest in leprosy in the 1940s was a reflection of Nationalist pride. The reality however, is that a more positive attitude probably developed as a response to early indications of the efficacy of dapsone. Dapsone was hailed enthusiastically as a wonder drug after it was demonstrated by Cochrane (1961) that it could be effective as a cure for leprosy.

With independence, "The Indian Council of the British Empire Leprosy Relief Association", was renamed "*The Hind Kusht Nivaran Sangh*". As such it organised "The All India Survey Party" to conduct studies on subjects related to leprosy on a national level. "The All India Survey Party" established P.T.S. centres (Propaganda-publicity, Treatment and Surgery centres) to conduct surveys from which an overview of the problem of leprosy could be assessed. Further developments were made in the period between 1954 and 1955. The Ministry of Health, Government of India, responded to a recommendation by "The Central Council of Health" to establish a "Committee For The Control Of Leprosy". Based on limited sample surveys the Committee reported that there were approximately 1,500,000 cases of leprosy nation-wide. Of this number only 10% were receiving treatment (Directorate General Of Health Services 1981). On the basis of the findings of this committee The National Leprosy Control Programme (N.L.C.P.) was

launched. The objectives of the N.L.C.P. were four fold:

1. The reduction of incidence of disease.
2. The reduction of duration of disease with consequent reduction in transmission risk.
3. The reduction of physical and psycho-social effects secondary to the disease.
4. The reduction in financial burden to the community.

The programme was to be reviewed quinquennially under what became instituted as "The Five Year Plan" strategy. With the culmination of each period, recommendations were made in an attempt to meet the challenge of the development of the disease relative to the spiralling population figures (Deish 1969).

6.1.2. NATIONAL LEPROSY ERADICATION PROGRAMME

In 1981, during the 6th quinquennium, radical developments were made. The then Prime Minister, Indira Gandhi (1981), instigated a major new initiative. She strove to mobilise not only the bureaucracy but also prominent leprologists, the Government's Science Advisory Committee, and WHO to draw up an ambitious "eradication" programme.

A "Working Group On The Eradication Of Leprosy" was established to formulate a strategy for the programme (WGEL 1982). Swaminathan (The chairman of the working group) rejected the "More Of The Same" approach and endorsed an "Integrated Action Plan" that became recognised as a "Milestone Chart".²³

Undoubtedly the major impetus at this stage came from the WHO who had instigated a study on the chemotherapy of leprosy (WHO 1982). Their recommendations on the

23 (a) *Mass Awareness And Participation In The Sixth Plan During The Remaining Period (1982-85)* - Promotion of the acceptance of leprosy by society as any other disease for which cure is available through mass education, was to be a major programme thrust.

(b) *Attack Phase* - Intensified chemotherapy campaign : Seventh Plan (1985-90)

(c) *Consolidation Phase* - Eighth and Ninth Plans (1990-2000) (From Misra 1993 pg 79)

use of multi drug therapy brought about revolutionary changes.

Reorganisation of bureaucracy was demonstrated by the establishment of the National Commission For The Eradication Of Leprosy and the National Leprosy Eradication Board. These institutions were established for the structure of policy, programme implementation, monitoring and evaluation at the national level and executive level respectively. Supported by government and voluntary organisations, similar bureaucracy was established at state level.

The National Leprosy Eradication Programme (NLEP) is essentially a vertical programme with emphasis directed at providing exclusive services for leprosy treatment away from public health domain. Accepted national policy was that multi drug treatment (M.D.T.) would be introduced to all 201 hyperendemic areas (i.e. prevalence >5 per 1000) in a phased manner with effect from 1983 (NLEP 1987). A prerequisite to implementation was adequate infrastructure at district level. In 1983 only two districts were able to satisfy infrastructure requirements. By April 1992, 135 districts were covered and an estimated 75% of registered cases (1.5 to 1.6 million) were treated with M.D.T. (Misra 1993).

6.1.3. THE EFFECTS OF MULTI DRUG THERAPY

In retrospect it is evident that M.D.T. has been more effective than dapsone monotherapy. Patients are cured in finite periods as opposed to dapsone therapy whereby many required treatment for life. Consequently, prevention of relapse and drug resistance has been more successful.

More broadly defined, the success of M.D.T. includes that positive results have contributed to the demystification of leprosy, thereby making it more accepted into mainstream medicine. As such it has contributed toward the weakening of stigma. Not the least problem with the implementation of M.D.T., however, is the potential for long term complacency following early success. The duration of treatment, although greatly reduced is still protracted. Furthermore, M.D.T. does not effect the

clearance of dead bacilli which means that clinical complications may still continue after treatment (Noordeen 1991). This has important implications for the deformity rate. It is the characteristic deformities, above other signs of the disease, that contributes to the perpetuation of stigma. Rao (1992) found that 89.6% of respondents in the community he studied indicated that deformity or ulceration was a symptom of disease. Dermatological signs were recognised as indicating leprosy by only 19.1% of respondents. An implication is that a significant majority of cases are not recognised by the community as leprosy. M.D.T. has been shown to reduce the prevalence of leprosy. In many areas, however, incidence figures have not been reduced. This situation continues to confound leprologists and epidemiologists alike (Noordeen 1991, Bannerji 1992, Rao 1992, Misra 1993).

6.1.4. EVALUATION OF THE N.L.E.P.

Since 1986 the N.L.E.P. has been evaluated on four occasions, jointly and independently, by teams of officials representing both the WHO and the Government of India. These evaluations are summarised by Misra (1993) and Rao (1992) who identified similar features for criticism.

Concern was expressed for the hyperendemic areas where there was still inadequate infrastructure to implement M.D.T. and for areas of moderate or low endemicity (i.e. < 5 per 1000) where it was not even planned to implement M.D.T. Since the inception of M.D.T. it has been demonstrated that it is possible to register a 10 fold decrease in prevalence in a five year period. This is conditional on treatment being applied to 85% of patients (Noordeen 1991). However there are a number of issues that stem from this claim related to questions that have been voiced by a number of researchers:

How reliable are the surveys?

How great is the extent of undetected leprosy?

To what extent do the number of registered cases reflect the full extent of the situation?

6.1.5 SURVEY RELIABILITY

The quality of the NLEP was found to be substandard in performance at all levels. However the most serious criticism was levelled at the Sample Survey Assessment Units (S.S.A.U.s). The quality of surveys undertaken in urban areas and in schools was uniformly poor. It was also found that there was a gross underestimation of cases in some districts (NLEP 1991).

Most field surveys were considered to be unreliable due to poor quality of reporting and compromised integrity of data collection. Rao found that data was frequently fabricated to meet time bound approaches. The Danlep project (cited by Banerji 1992) adopted an approach that actively involved communities in the Rajanandgaon district of Madhya Pradesh. Their approach was discrete and did not involve a house to house search. They demonstrated that it was possible to discover as many as 50-100% more cases than those found under the N.L.E.P. scheme. Under the N.L.E.P., poor examination performance by paramedical workers was exacerbated by cultural restrictions that limit exposure of the body, especially amongst women.

Noordeen (1991) discussed the problem of undetected cases and suggested that they comprise subjects who are unaware that they have the disease. Many of these will be paucibacillary cases with a tendency for self healing, but some will progress to become more serious. Leprosy being an extremely complex disease, presents particular difficulties for diagnosis in its subclinical form. The spread of infection into a community by subclinical carriers has not been monitored. This and the phenomenon of self healing may be confounding variables of considerable effect in epidemiological studies. Incidence is difficult to calculate. The time relationship between the earliest dermatological signs and the onset of disease varies greatly. This factor complicates other variable features of the disease so that it eludes definition of character. The multiplication of the bacillus is slow and incubation periods have not been verified. Host immunological deficits, thought to contribute to the development of disease type, remain topics of speculation, as do the portals of entry and exit of the bacilli (Noordeen 1991).

6.1.6 CAN LEPROSY BE ERADICATED BY THE YEAR 2000?

Referring to Indira Gandhi's call for commitment to eradicate leprosy in India by the year 2000, Professor Bannerji said:

"While it is understandable that a political leader should have coined such a catchy slogan, identification of some of the foremost leprologists and scientists of the country and of WHO with this slogan is most astonishing. Those even with the most elementary understanding of the epidemiology of leprosy in India could have realised that such an expectation is utterly untenable."

(Foreword in Leprosy in Rural India, Rao 1992)

The WHO have, however, proposed a less ambitious though widely misunderstood strategy. The Resolution of The Forty-Fourth World Health Assembly (1991) suggested that leprosy could be "eliminated" as a public health problem by the year 2000. Elimination is not synonymous with eradication but implies an acceptance of a level of disease such that transmission of infection will be minimal. This level, currently defined as a prevalence of 1:10,000, is deemed not to present a public health problem. This is an arbitrary figure adopted on the basis of a supposition that at such a level the disease burden on a community will be significantly limited. Even this ideal seems improbable in the Indian context given the findings reviewed. Noordeen (1991), who has contributed the most extensive studies of the epidemiology of leprosy in India, suggests with caution that it may be possible. However the reservation he states is that it will require an immense commitment.

The most searching study of the N.L.C.P. was conducted by Rao (1992) who identified the Chingleput district as being representative of high endemic areas targeted by the programme. Dr. Rao's insight into the grass root implementation of the programme has been presented in his fearlessly outspoken book, "Leprosy in rural India" (Rao 1992). A gross disregard for patient well being at every level is profiled against a backdrop of corruption, negligence and incompetence of such bewildering proportions that it suggests chaos. If the Chingleput district is a valid representation, as Rao suggests, an implication is that epidemiological data published over the 25 year period is not valid. Apart from individual attempts to describe characteristics of

the disease, no concerted effort has been made to conduct an independent systematic epidemiological study. Figures published by State Governments were furnished by State Leprosy Offices. Relating to the Chingleput district in the state of Tamil Nadu, Rao reported that prevalence figures presented by the State Leprosy Officer differed markedly from prevalence figures forwarded from the District Leprosy Officer. It was explained that on examination of the lists, large numbers of patients had moved away from the Chingleput district. These cases were deleted from both district and state lists even though they had in all probability not left the state. It appears likely that they would have migrated only to adjoining districts where most would have been reregistered as new cases.

6.1.7. DISABILITY: THE RESIDUAL EFFECT

Assuming the goal of elimination is reached, the effects of leprosy will be evident well into the twenty first century. It appears ironic that although disability and deformity are the most glaring characteristics of the disease, relatively few epidemiological studies have been conducted on the extent or effects of the problem. Banerji (cited by Rao 1992) called for an alternative perspective on research priorities. His suggestion was that research should be led by the requirements of leprosy patients themselves and the community at large. It is in this field that deformity is still overwhelmingly and erroneously considered a major symptom of active disease. Cultural perception and meaning of leprosy, patient response to services and a concerted commitment to develop an interdisciplinary approach to leprosy should take precedence over laboratory research.

Noordeen (1991) cites an estimation of three million people as representing the figure of leprosy disabled subjects worldwide. According to his estimate, if 75% of registered cases of leprosy are found in India the indication is that 2,250,000 Indians are leprosy disabled. The author suggests that the real figure representing leprosy disabled may be very much higher.

The classification of disability and the calculation of disability rate are inadequate

measures of the extent of disablement caused by leprosy and present a limited perspective of the enduring consequences of the disease. The WHO (1988) published a simple three grade system of classification for the collection of data regarding disabilities.

Hands and Feet

- Grade 0: No anaesthesia, no visible deformity or damage.
- Grade 1: Anaesthesia present, but no visible deformity or damage.
- Grade 2: Visible deformity or damage present.

(WHO 1988)

"Damage" includes ulceration, shortening, disorganisation, stiffness, and loss of part or all of a foot or hand.

Accepting that a large number of patients will present for treatment as a result of neuropathy related trauma in the first instance, there is some justification for calculating a disability rate for new cases. However, the development of disability is clearly dependent on the duration of disease and the type of disease (Thappa *et al.* 1990, Kartikeyan and Chaturvedi 1992, Saha and Das 1993). Age of onset of disease has also been considered by some to be an independent variable effecting disability (support for this hypothesis is weak). The recognition of higher disability rates amongst those of advanced age is more likely to reflect the effect of duration of disease. The studies cited here as reporting age related correlation with increased disability rate were cross sectional studies (Thappa *et al.* 1990, Saha and Das 1993).

A disability rate calculated at initial presentation is restrictive in that it does not reflect the probability of future trauma as consequences of neuropathy. Disadvantaged by neuropathy in childhood, or early adulthood, the prospect of decades of vulnerability must suggest a greater probability of disablement. Speedy detection and inclusion into a M.D.T. regime are likely to reduce the development of neuropathy. However, the onset of neuropathy may present after the course of treatment is complete due to the residual concentration of dead bacilli (Noordeen 1991).

By extrapolating figures from The NLEP Statewise Leprosy Profile (1991) and figures relating to estimated cases from "The Agenda Notes of The National Conference Of Voluntary Organisations" (Kurup *et al.* 1992) an estimate of the number of leprosy disabled in India over the period 1981-1991 has been calculated. My calculation is limited in that it does not reflect those subjects who have developed disability after discharge.

A disability rate calculated by Mehta *et al.* (1992, 1993) is based on the following formula:

$$\text{Disability} = \frac{\text{Total Disabilities}}{\text{Registered New Cases}} \times 100$$

<i>On Record</i>	<u>2,184,299</u>
<i>Discharged</i>	<u>5,430,379</u>
<i>Sub Total</i>	<u>7,614,678</u>
 <i>Estimated Number Unregistered</i>	 <u>1,748,700</u>
<i>Total</i>	<u><u>9,363,378</u></u>

Assuming a disability rate of 33%, **3,089,914** subjects in India may be disabled. (This estimate does not take into account the number of deaths that may have occurred over that period). 33% disability rate refers to disability amongst registered cases recorded in Pune. It is based on the mean of disability rates reported over a period from 1981 to 1984 by Mehta *et al.* (1992). (Disability rates reported after 1984 refer to new cases only.) Saha and Das (1993) reported a disability rate of 22.31% whilst an earlier study reported 44.3% (Hassan 1977). The estimate presented here assumes that the population studied by Mehta *et al.* in Pune is representative of the urban population of leprosy sufferers.

Quantitative analysis may represent a reliable indication of the extent of an issue. The orderly presentation of objective findings, however, sometimes fails to convey the human impact of the situations they represent. Dr Rao (1993) should be commended for his graphic representation of the quality of service available to the population he studied, which was considered representative of populations in high endemic areas. (Rao's broad criticism of Governmental and Voluntary organisations was uniformly severe.)

"The facilities at the way side clinics are so negligible that the entire team waits in the congested atmosphere in the van surrounded by drugs and records with about 80 to 100 patients. It is to be noted that one hour of clinic time is the only time of contact between the patients and the team in a whole month. Due to time constraints the treatment team is in such a great hurry that they cannot even spare a minute to each patient. The medical officer if he/she ever attends, does not have time to assess the cases systematically. Even if a physiotherapy technician was present it could not been possible for him to attend to more than 2 or 3 of the total deformed patients. The pharmacist who sits in the van is just not able to explain the mode of intake of drugs to the patients. Even the very limited medications are not supplied in sufficient quantities for taking care of the other routine illnesses of the patients. Even if some medication for treatment for inter-current ailments are given, they are given only for a day or two and the patients have to wait for a full month for expressing their difficulties to the team regarding that particular illness again. The drugs in most of the instances are handed over to the patients into their bare wet hands. The tablets being so fragile that they crumble very easily. Only a few patients who were regular bring some containers of their own.

If some patients have got ulcers they are just given some powders and asked to dress them selves and most of such patients do not have fingers at all or have only bent and useless fingers to dress with." Rao (1992 p.p.205-206) reporting on the National Leprosy Control Programme.

At grass root level, poor supervision resulting in lack of knowledge and skills related to disability prevention has been demonstrated by paramedics and supervisors (Rao and Bhusari 1992, Govt. of India 1990). The inadequate training, implicated as a cause for poor performance, is symptomatic of an insidious apathy reflecting the general attitude toward the disease. N.L.E.P. has been criticised for increasing professional insecurity with the inevitable overlapping of skills giving rise to fears of encroachment. Little is done to promote the enthusiasm of workers who feel stigmatised by the community and threatened by social distancing between doctors and paramedical workers (Premkumar and Dave 1992).

6.1.8 INDICATORS OF APPROPRIATENESS: A CRITERION MEASURE FOR THE EVALUATION OF THE APPROPRIATENESS OF PODIATRIC ORTHOSES

Accepting that ethnocentric bias may affect his views on the state of leprosy impairment control, the author sought valid criteria, from external sources, by which appropriate treatment may be recognised in India. To accomplish this objective a Delphi questionnaire was designed to solicit a consensus, on the issue of appropriateness, from senior Indian field workers. All the subjects, who were approached, have published works relating to aspects of leprosy impairment control.

6.1.8.1 The Delphi technique

Since its conception in the 1950s when it was used by the Rand Corporation for use in defence related problems (Helmer and Rescher 1959) the Delphi technique has been applied extensively. As a method for scrutinising policy implementation, it has been used to test the existence of consensus in the perception of objectives and establishes the level of consistency in interpreting such objectives (Hakim and Weinblat 1991, Toumbourou and Hamilton 1993). Similarly, it has been used as a forecasting method where a consensus regarding developments was considered a valid indicator for future developments (Prebble and Rau 1986). As a method of

consensus testing, it has been applied to establish differences or to clarify alternative opinions from individuals among diverse reference groups. As such, it has been applied in conflict resolution (Hartman 1981) and role clarification (Shelton 1984). As a method for information sharing and policy development amongst health disciplines, it has been used to determine diagnoses (Zadinsky and Boettcher 1992, Whiting 1994) and to ascertain criteria for professional competence (Davies and Van der Gaag 1992). It was also used by Mobily *et al.* (1993) to validate definitions and activities considered to be important in the implementation of nonpharmacological pain management.

6.1.8.2 Characteristics of the Delphi technique

The method is usually adjusted to suit the individuality of diverse applications, but there are fundamental elements which characterise the procedure: i.e. The method is targeted at broadly homogenous groups, it is anonymous, it exercises controlled feedback and demonstrates group consensus statistically.

Following the advice of Delbecq *et al.* (1975) sample size should be dictated by the homogeneity of the group and the nature of the investigation. A large sample is necessary if the principle reason for conducting the procedure is to develop awareness within a group, or where diverse reference groups are involved. The purpose of this investigation however was to gather opinions based on experience. For this purpose, Delbecque *et al.* suggest that a group of ten to fifteen participants is adequate for a homogenous group. Increasing the size of a homogenous group beyond 30 will not result in more information and only increases administration difficulties.

Anonymity between participants should be maintained throughout. The rationale for this approach is that consensus is not confounded by conforming behaviour. Such behaviour is, by report, a prevalent feature of group dynamics in interacting groups (Delbecq *et al.* 1975). With anonymity, the expression of covert judgements is not inhibited by peer admonition, nor the effects of status incongruity (eg. the endorsement, without conviction, of the opinions of higher status members). Furthermore, the implied threat of dominant or hostile personalities is eliminated.

Anonymity suppresses hidden agendas and covert group dynamics thereby extending to all participants the opportunity to contribute to the group product and influence the decision outcome.

Methodological details vary considerably according to the requirements of individual studies. The general approach has been that sequential, structured questionnaires have been used for participants to rank, or rate, responses to indicate his/her priorities related to topics of interest. On receipt of returned questionnaires, information is collated and analysed. In more protracted procedures participants are encouraged to resolve differences of opinion. Hakim and Weinblat (1993) recommend that information, in the form of a statistical analysis, should be dispatched to participants at subsequent rounds of the procedure. Feedback analysis should include the frequency with which participants selected answers, with the mean and/or median and one measure of dispersion. Individuals are asked to reconsider the scores applied previously (in the light of aggregated responses of all members) and in this manner, consensus is generated. Feedback to participants should be controlled so that only succinct information, directly relevant to the investigation is encouraged. It has been suggested that controlled feedback reduces the obscuring "noise" of divergent discussion. Where reported outcome is strictly confined to statistical measures of agreement or dissent, it is considered that bias produced by the dictate of vociferous minorities is screened out (Hakim and Weinblat 1993).

The technique has been used for soliciting opinions from diverse study groups. Panellists have usually (though not exclusively) been recruited by merit of an intimate academic or experiential association with the topic under investigation. Acknowledged expertise or influence may validate a choice of participants, however, such attributes per se are insufficient for the inclusion of participants. Delbecq *et al.* (1975) suggest that commitment to the investigation and motivation to comply with the demands of procedure are fundamental. The "nature of the respondent panel, the obligations of participants, the length of time the Delphi process will take and the information that will be shared among participants" are variables likely to effect the co-operation of invited individuals and should be declared at the initial stages of

recruitment. Feedback analysis should include the frequency with which participants selected answers, with the mean and/or median and one measure of dispersion. Individuals are asked to reconsider the scores applied previously (in the light of aggregated responses of all members) and in this manner, consensus is generated.

6.2 METHOD

An invitation was dispatched to 15 senior leprosy field workers with a request to participate in a Delphi investigation. The communication explained the procedure and detailed the level of commitment required from each participant (See Appendix 4). With each letter I included the following question:

"What are the criteria for measuring whether treatment is appropriate for leprosy patients in India?"

Consider only the treatment of complications secondary to nerve damage.

Each participant was asked to submit a maximum of 5 responses. Ten subjects responded positively to the request to participate and returned completed questionnaires. The criteria submitted were collated and a second schedule was composed (see Appendix 5).

The responses were wide ranging in their emphasis. There were a total of 38 distinct criteria submitted (some respondents submitted criteria that had been suggested by others). When collating the responses, it became clear that the criteria submitted could be categorised into 6 groups.

1. Objective criteria:

These suggestions related to observable improvements in physical impairment. There were seven responses suggesting such indicators.

2. Functional criteria:

These suggestions related improvements in mobility. Five such indicators were suggested.

3. Psychological criteria:

These suggestions related to improvements in self perception and motivation. There were 4 suggestions relating to these issues.

4. Sociological criteria:

These suggestions related to improvements in employment and integration. There were 6 suggestions relating to these issues.

5. Economic criteria:

Five suggestions relating to cost effectiveness and resource availability were contributed.

6. Epidemiological criteria:

There were five suggestions relating to prevalence and patient satisfaction.

Wherever possible responses were presented in the form in which they were received. The wording of responses was only altered where it was necessary to preserve the logic of the investigation. Care was taken to present the responses in a form which did not compromise the meaning the respondents intended. A proforma comprising the six sets of criteria was dispatched to the Delphi members with a request that they should rank each response within the sets that had been composed. The proforma also included a seventh task. The Delphi members were asked to consider a list of the groups of responses. Members were requested to rank the groups listed to indicate how each member would prioritise the groups as indicators of the appropriateness of treatment, specifically for plantar ulceration.

6.3 RESULTS

The responses to the seven groups of criteria are presented in Tables 50 to 57.

Table 50: Delphi Responses Relating to Objective Criteria

Objective Criteria	Responses n = 10											
	A.P.	D.P.	V.K.	H.S.	M.G.	E.F.	S.S.	S.K.	B.R.	A.M.	Mean	Rank
Treatment may be considered appropriate where:												
there is a quantifiable reduction in cracks/callous formation on the plantar surface of the foot.	1	4	5	4	1	3	4	4	4	5	3.5	4
the treatment is associated with a reduction in blistering on the plantar surface of the foot.	2	6	6	7	2	7	7	5	6	7	5.5	6
treatment is associated with a return of sweating.	6	7	4	5	7	2	6	6	7	6	5.6	7
there is an optimum return of nerve function where nerve damage is reversible.	7	1	2	1	6	5	1	1	2	3	2.9	3
the treatment facilitates early detection of nerve damage before the damage becomes irreversible.	3	2	1	2	3	6	3	3	1	1	2.5	1
there is an improvement in motor power (VMT confirms).	5	5	7	6	5	4	5	7	5	4	5.3	5
there is an improvement in sensory perception in affected parts.	4	3	3	3	4	1	2	2	3	2	2.7	2

Table 51: Delphi Responses Relating to Functional Criteria

Functional criteria	Responses n = 10											
	A.P.	D.P	V.K	H.S.	M.G	E.F.	S.S.	S.K.	B.R	A.M	Mean	Rank
there is sufficient mobility for the patient to continue employment without pain or associated swelling of feet.	1	2	5	4	1	4	4	1	5	4	3.1	4
there is provision of a long term solution for a current problem i.e. recurrence free results.	3	3	4	2	2	3	3	4	3	3	3.0	3
the treatment anticipates other problems likely to arise from the same basic cause (nerve damage) and helps to avoid them.	4	1	2	1	4	5	1	2	2	1	2.3	1
the treatment gives optimum restoration of the form and function of the foot when irreversible nerve damage has resulted in deformity and disability.	2	5	1	5	5	1	5	5	4	5	3.8	5
the treatment is easy for the patient to comply with.	5	4	3	3	3	2	2	3	1	2	2.8	2

Table 52: Delphi Responses Relating to Psychological Criteria

Psychological Criteria	Responses n = 10											
	A.P.	D.P	V.K	H.S.	M.G	E.F.	S.S.	S.K.	B.R	A.M	Mean	Rank
there is a general improvement in compliance after signs of restoration.	1	4	4	2	3	1	3	2	3	3	2.6	3
patient education regarding the detection and treatment of nerve damage has been advanced.	4	1	3	1	2	2	4	4	4	4	2.9	4
appliances etc. are such that patients can wear them without attracting undue curiosity.	2	3	1	3	4	4	2	3	2	1	2.5	2
the treatment meets with patient expectations of overcoming stigma.	3	2	2	4	1	3	1	1	1	2	2.0	1

Table 53: Delphi Responses Relating to Sociological Criteria

Sociological criteria	Responses n = 10											
	A.P.	D.P	V.K	H.S.	M.G	E.F.	S.S.	S.K.	B.R	A.M	Mean	Rank
treatment does not interfere with employment or other social/family activities.	1	4	4	2	1	1		1	1	1	1.6	1
patients and health workers are willing to carry out the treatment.	3	3	1	3	2	6		5	3	5	3.4	5
the treatment is compatible with available health facilities.	2	5	2	4	6	2		6	2	4	3.3	4
the patient's quality of life has been improved.	4	1	5	5	5	3		2	5	2	3.2	3
the treatment helps the patient's family and the neighbourhood to understand and react positively to the patient's predicament.	5	2	3	1	4	5		3	4	3	3.0	2
there is an infrequent necessity to visit the clinic or workshop (perhaps once in three months).	6	6	6	6	3	4		4	6	6	4.7	6

Table 54: Delphi Responses Relating to Economic Criteria

Economic criteria	Responses n = 10											
	A.P.	D.P	V.K	H.S.	M.G	E.F.	S.S.	S.K.	B.R	A.M	Mean	Rank
Treatment may be considered appropriate where:												
the price is within the gross salary of a hospital physical therapist (This, in India is currently about Ind.Rs.750/- this figure is not to be taken at its exchange value but is the amount equivalent to the salary of the therapist for one week.)	5	4	3	5	1	2		5	5	4	3.4	4
the treatment is cost effective.	4	1	1	3	2	1		2	1	2	1.7	1
there is sufficient funding available to implement and sustain the treatment.	1	2	2	2	5	4		4	2	3	2.5	3
the treatment is practicable in terms of available resources.	2	3	4	1	4	5		1	3	1	2.4	2
modified footwear is durable (it should last for at least two years).	3	5	5	4	3	3		3	4	5	3.5	5

Table 55: Delphi Resonses Relating to Epidemiological Criteria

Epidemiological criteria	Responses n = 10											
	A.P.	D.P	V.K	H.S.	M.G	E.F.	S.S.	S.K.	B.R	A.M	Mean	Rank
the long term effectiveness of treatment can be effectively followed up.	4	4	4	5	5	1		3	5	5	3.6	5
the extent of the problem of preventable disabilities (taking community as a denominator and taking cumulative patient total as numerator) is considered great enough to warrant action.	3	2	5	4	1	5		2	4	3	2.9	3
a high proportion of patients are satisfied with the available treatment.	1	1	2	2	2	2		4	1	2	1.7	1
a high proportion of patients avail themselves of the available treatment.	2	3	3	1	3	3		1	2	1	1.8	2
a larger population of patients who need services stay in an area where services are available.	5	5	1	3	4	4		5	3	4	3.4	4

Table 56: Delphi Ratings of Groups of Criteria

Ranking of indicators of appropriate treatment for ulceration.	Responses n = 10											
	A.P.	D.P	V.K	H.S.	M.G	E.F.	S.S.	S.K.	B.R	A.M	Mean	Rank
Epidemiological indicators.	6		4	6	2	1	6	6	5	3	3.9	6
Economic indicators.	2		2	4	3	5	2	5	3	1	2.7	3
Sociological indicators.	4		3	2	6	2	1	2	1	2	2.3	1
Psychological indicators	5		6	3	5	4	3	3	2	6	3.7	4
Functional indicators.	1		5	1	1	3	4	1	4	5	2.5	2
Objective indicators	3		1	5	4	6	5	4	6	4	3.8	5

6.3.1 GROUP CONSENSUS

It is emphasised here that although the mathematical aggregation of votes identified group priorities, as a polled response, differences of opinion were not resolved. An implication of this observation is that the consensual validity, of the suggestion that there are indicators of appropriateness (except for the Sociological and Epidemiological indicators) is slight. All further interpretation is therefore subject to this limitation.

6.3.2 THE COMPATIBILITY OF THE AIMS OF THE PROJECT WITH THE CRITERIA SUGGESTED BY THE DELPHI PARTICIPANTS

A total of 32 criteria were submitted by the participants, of this number 9 (all the "Objective" criteria and two "Psychological" criteria) were directly related to the prevention, restoration or control of nerve dysfunction. Orthotic treatment does not aim to address the problem of neuropathy per se, consequently the intervention does not satisfy these criteria. Twenty three of the suggested criteria (72%) reflect fundamental issues that influenced the design and assessment of the project. Based on this observation, the author suggests that the aims of the study were appropriate.

6.3.3 THE COMPATIBILITY OF THE RESULTS OF THE STUDY WITH THE CRITERIA SUGGESTED BY THE DELPHI PARTICIPANTS

The participants were requested to rank the groups of criteria to indicate the priority of each group, relative to its importance as an indicator of appropriate treatment for plantar ulceration. There is no quantitative method for correlating the results of the study with the criteria submitted by the Delphi participants. The intervention will be considered "appropriate" if the results and the inferences drawn from the results concur with the criteria suggested.

The participants considered the "Sociological" criteria to be most relevant when considering treatment for plantar ulceration. "Functional" and "Economical" criteria

were ranked second and third respectively. As stated above, the "Objective" criteria and two of the "Psychological" criteria related to nerve dysfunction and are not relevant for further discussion. The group of criteria that was ranked lowest was that categorised as "Epidemiological". This was a surprising result as the author considered that the relevance of such criteria, in the context of this aspect of the study, would be salient.

6.4 DISCUSSION

This discussion proceeds by considering the criteria, suggested by the participants. An aim is to demonstrate the association between the criteria suggested with the findings and inferences drawn from the project.

6.4.1 SOCIOLOGICAL CRITERIA

Each criterion within this group will be discussed in order of rank.

6.4.1.1 **Treatment may be considered appropriate if it does not interfere with employment or other social/family activities.**

Seven Delphi participants considered the above statement to be the most important sociological indicator (one other ranked it second whilst two ranked it fourth).

The social and economic disablement of the leprosy impaired continues to be a major concern. Enlightened individuals and agencies are developing rehabilitation enterprises through which it is hoped that the leprosy impaired may gradually be reintegrated into mainstream Indian society. However it is economic self sufficiency for the disabled that appears to be the principal objective motivating most charitable and governmental agencies. The establishment of vocational training programmes, where the objective is to assist those disabled through leprosy to become economically self sufficient, is undoubtedly a pressing issue (Mehta 1992). The findings of Krishnan and Gotam (1992) recorded prevalence rates of between 9.16 and 17.31 per thousand amongst leprosy sufferers living in a Pune slum with a population of 4915 (i.e. between 45 and 85 individuals). Such slums comprise predominantly migrant workers who have been dislocated from traditional Indian agricultural communities. A priority consideration for such a population is that it should develop sustainable means of survival.

In more stable traditional communities the extended family structure may provide

some support for impaired members. However, age and gender dictated family roles must be upheld if the destabilisation and erosion of the family structure is to be prevented. Karitkayan and Chaturvedi (1992) conducted a study of Indian agricultural workers affected by leprosy. They found that patients with deformities were constrained to continue working to avoid loss of dignity and dependence on family members. It is suggested that recognition of, and support for, the family structure are pivotal features upon which the stability of Indian society is dependent.

Foot orthoses do not impede the flow of family and other social commitments. No subject in this study suffered any loss of earnings, or any other employment related disadvantage, as an effect of wearing orthoses. Contrary to interfering with social activities the orthoses were associated with a perceived (and perhaps objective) improvement in social activity (see 5.5.2.14). It is proposed therefore that the treatment met the first criterion.

6.4.1.2 Treatment may be considered appropriate if it helps the patient's family, and the neighbourhood, to understand and react positively to the patient's predicament.

Issues relating to the meaning of the disease for the individual and Indian society were discussed extensively in Chapter 5. Deformity and the disablement of the impaired to fulfil the ritual and temporal roles prescribed by Indian culture does lead to social isolation and loss of identity. In the context of the close social interaction that characterises Indian society, isolationism will be perceived as deviant (Waxler 1981, Volinn 1989). This possibly explains the relevance of the term "*predicament*". There is no evidence to suggest that the intervention did help the subjects' close associates to "*understand and react positively to the patient's predicament*". However in the context of this study this particular criterion may not be particularly relevant. The majority of subjects live in colonies populated by similarly impaired individuals for whom the "*predicament*" would be a common experience. What did transpire was that some of the spouses of subjects in the trial did encourage their partners to comply with the intervention.

6.4.1.3 (i) Treatment may be considered appropriate if it is compatible with available health facilities.

This project was based on a pragmatic approach to available health facilities. The facilities and materials available at Dr Bandorawalla leprosy hospital were adequate for the low resource intensive approach that was tested. Other factors, that influenced the sustainability of the service, were the subject of Chapter 4. Some of these factors had not been adequately considered in the planning process. The results, however, do suggest that a sustainable, and therefore "compatible" service will be feasible where facilities and services are similar to those at Dr Bandorawalla leprosy hospital. Based on this premise I suggest that the treatment met the criterion ranked third in the "Sociological" group of criteria.

(ii) Treatment may be considered appropriate if patients and health workers are willing to carry it out.

This criterion was ranked joint third with the previous criterion.

There was a strong endorsement of the intervention by the subjects in the trial (see chapter 5).

It was considered earlier that stigma may be a significant factor affecting compliance (this issue was commented on extensively in Chapter 5.4). It is possible that this project demonstrated an effect of destigmatisation. The ready compliance and apparent enthusiasm for the intervention may be an effect of perceived care. It may be that the effects of the intervention cannot be considered independently of the effects of perceived concern administered either by me or the technician. However, the intervention did not require high levels of effort on behalf of the subjects. I consider this to be an important factor as compliance, particularly amongst those suffering chronic disorders, is poor (Volinn 1983).

Valencia (1988) stressed that it was important that health providers are understood in the context of their work and are given recognition for their efforts. Without

restructuring incentives to facilitate broader recognition (e.g. formal awards and benefits) health givers will remain inadequately motivated. It is her strong contention that the significant role of health-care givers, in leprosy, has been understated. This may explain why Rao (1992) reported such deplorably poor attitudes amongst leprosy paramedical workers.

The issue of workers being "*willing to carry out the treatment*" extends to all aspects of care and is probably more dependent on recognition and reward rather than the nature of the treatment. It may be that the technician who carried out the supply and review of orthoses is an exceptional character. His attitude and dedication are remarkable. He maintained an enthusiasm for the orthotic approach throughout the experimental period.

On consideration of the results presented in chapter 5 and accepting the limitations suggested, it is proposed that the intervention did meet the criteria ranked third.

6.4.1.4 Treatment may be considered appropriate if the patient's quality of life has been improved.

An indication, from the results of the interview survey, was that most of the subjects perceived beneficial changes in their participation in social activities since their ulcers had resolved. Since ulcer resolution was associated with the intervention, it was suggested that the intervention was a factor that altered the attitudes and actions of the subjects (see 5.6.3.).

This may not be a particularly reliable indicator as such changes in perception may be due to other variables (e.g. social desirability factors or the destigmatising effects of caring attitudes). From the diagnosis to the supply of orthoses, procedures require that clinicians should handle the patients' feet. It is apparent that for many, such an act is considered a radical expression of acceptance and as such it is likely to promote a sense of self esteem. In this study, it is possible that the effects of the instrument of treatment cannot be considered independently of the act of treatment. It is suggested,

however, that the effects of personal attention are transient compared to the long term effects of ulcer resolution. Based on the face validity of this suggestion the author proposes that orthotic intervention does meet the fifth "Sociological" criterion

6.4.1.5 Treatment may be considered appropriate if there is an infrequent necessity to visit the clinic or workshop (once in three months)

Although the intervention did not require high levels of effort from the subjects, it did require diligence regarding footwear. This was an issue of importance as the integrity of an orthosis is compromised when the footwear that supports it becomes misshapen. The author suggests that for orthotic treatment to be effective a requirement is that patients should present for assessment at two month intervals. The criterion of appropriateness considered here is "*an infrequent necessity for patients to visit the clinic or workshop (perhaps once in three months)*". Although this was the lowest ranked of the "Sociological" criteria it is, nonetheless, an issue of note. The orthotic treatment does not meet this criterion.

6.4.2. FUNCTIONAL CRITERIA

6.4.2.1 The treatment may be considered appropriate if it anticipates other problems likely to arise from the same basic cause (nerve damage) and helps to avoid them.

Based on the evidence considered in chapter 1, it is reasonable to suggest that the most debilitating pedal problems, related to anaesthesia, are secondary to ulceration. Secondary infection and hyperaemia are implicated in the degenerative process of osteoporosis which predisposes the foot to pathological fractures and absorption of bone tissue (Kulkarni and Mehta 1983, Enna 1988, Brand 1991,). Short foot and tarsal disintegration were cited as being effects of these processes. Tarsal disintegration may also be associated with conditions unrelated to ulceration. Massive invasion of bone by bacilli is reported to be a cause of rarefaction (Kulkarni and

Mehta 1983). Hypermobility and joint subluxation, as effects of aphasic or excessive subtalar pronation, are likely to be contributory factors leading to joint destruction and disintegration of the osseous architecture of the foot (see 2.1.9.2.).

The primary aim of the orthoses that were supplied was to address the exciting cause of ulceration through one, or a combination, of the following actions:

1. The deflection of pressure from a vulnerable area.
2. The redirection and redistribution of force.
3. The distribution of weight over an increased area of the foot.
4. Cushioning to reduce impact.

The orthotic approach also aimed to address the underlying pathomechanical activity that compromised the foot, thereby exposing it to excessive stresses. Secondary aims, therefore, included one or more of the following actions:

1. The correction of phasic joint kinematics by controlling the extent of subtalar pronation.
2. The accommodation of foot structure to facilitate optimum foot function.
3. The attenuation of effects of uncontrolled sub talar joint pronation.
4. The support and palliation of vulnerable areas of the foot.

Orthotic treatment does not aim to address the complication of infection. However, by reducing the period over which ulcers may be expected to heal the problem of secondary infection and hyperaemia, with associated sequelae, will be reduced. The author also suggests that orthoses do stabilise and enhance the mechanical function of the foot. If this hypothesis is correct, orthoses may significantly affect the pathomechanical processes that contribute to the destruction of the foot.

Indications are that the treatment does *"anticipate other problems likely to arise from the same basic cause (nerve damage)"* and that it does *"help to avoid them"*. On this basis, it is proposed that the treatment does meet the "Functional" criterion ranked as most important.

6.4.2.2 The treatment may be considered appropriate if it is easy for the patient to comply with.

Orthotic prescription was based primarily on considerations of gait, foot structure and vascular competence. Other considerations were the subjects' manual dexterity (particularly where subjects presented with hand deformity), their occupations and impressions of the intellect of individuals. Based on the consideration of all these variables, an appropriate orthosis was prescribed.

As stated earlier in this discussion, the treatment made very slight demands on the attention of the subjects. It is suggested, therefore, that the treatment was easy for the patients to comply with and does satisfy the second "Functional" criterion.

6.4.2.3 The treatment may be considered appropriate if there is provision for a long term solution for a current problem: i.e. recurrence free results.

The issue of ulcer recurrence was discussed in chapters 2 and 4 where it was suggested that, where recurrence was recorded, it appeared to be related to treatment default or lack of diligence. It was declared, however that a valid criterion (e.g. reliable medical records) with which recurrence could be compared was not available. It may be that recurrence would not have been predicted within the time span of the study.

Accepting the limitations suggested above, it is proposed that the evidence favours the suggestion that the treatment can be associated with recurrence free results and does therefore satisfy the third "Functional" criterion.

6.4.2.4 The treatment may be considered appropriate if there is sufficient mobility for the patient to continue employment without pain or associated swelling of feet.

In chapter 5.5.2.12. the results of the interview schedule detail the responses to a question which sought to ascertain how the subjects' experience of normal daily events had been affected during the experimental period. One of the variables considered was "work". Of 45 responses, 28 suggested that during the experimental period their experience of work had improved (of this number 6 subjects presented with unresolved ulcers). Of the 17 subjects (2 with healed ulcer sites) who suggested that their experience of work had not improved, 3 suggested that it had worsened (of these 3, one presented with a healed ulcer site).

These results suggest that for most of the subjects, the orthoses did not impede their ability to continue employment. It may be that for the majority the orthoses improved their ability to function. The author accepts that the perceived improvement may be an effect of factors other than the treatment, however, none of the subjects reported pain or discomfort associated with their orthoses after an initial period of accustomisation. These results support a suggestion that the orthoses did satisfy the fourth "Functional" criterion.

6.4.2.5 The treatment may be considered appropriate if it gives optimum restoration of the form and function of the foot when irreversible nerve damage has resulted in deformity and disability.

It was stated in chapter 2.1.10. that some orthoses are constructed to perform as a substitute for anatomical inadequacy. The accommodative effects of such orthoses are usually palliative. They are constructed to compensate for the loss of normal anatomical features with the aim of reducing excessive demands on the intact anatomy. In addition to the structure of the foot, such devices are also designed to address the altered mechanics that will result from deformity.

Whilst orthoses do not restore the form of the foot they do compensate for anatomical inadequacy and aim to restore optimum function to the deformed foot. Based on the assumption that these affects are realised it is suggested that the treatment does meet the final "Functional" criterion.

6.4.3. ECONOMIC CRITERIA

A weakness of this study is that it did not include a costing exercise. An objective was to enhance and maximise the existing human and material resources so that an increased financial burden would not be imposed on the host institution. The trial at Dr Bandorawalla Leprosy Hospital resulted in minimal additional expenditure for the institution. Many of the orthotic components were fabricated using off-cuts of microcellular rubber from the footwear department. Hospital personnel were not expected to increase their workload although some rescheduling of duties was required. It is emphasised however that this was a pilot study. Should other institutions consider implementing a similar service, the author would caution that the demand may be too great an imposition for a physiotherapy technician in isolation. A permanent "podiatry technician" may be required to service requirements. Based on the evidence from this investigation the author suggests that the introduction of podiatry technicians may be a cost effective measure. The remit of a podiatry technician could be extended to include all aspects of foot care. It is recommend that this suggestion should be investigated further.

6.4.4 THE RELIABILITY AND VALIDITY OF THE DELPHI TECHNIQUE

Delbecq *et al.* (1975) have presented a definitive review of issues related to small group decision making processes. They comparatively analysed Nominal Group Technique, Interacting and Delphi processes (pp. 15-35) on the following dimensions:

1. Overall methodology
2. Role orientation
3. Search behaviour
4. Normative behaviour

5. Equality of participation
6. Group composition and size
7. Method of conflict resolution
8. Closure to decision process
9. Utilisation of resources

They concluded that qualitative and quantitative evidence favours N.G.T. and Delphi Technique as methods for idea and estimate generation. The Delphi technique was considered to demonstrate the following characteristics that enhanced the decision making process:

1. Because respondents are required to commit thoughts to a written form, in isolation, the quantity and quality of ideas submitted is high.
2. Since there is no interaction between respondents, search behaviour is proactive.
3. The mathematical voting for the aggregation of group judgement facilitates equality of participation.
4. Anonymity allows freedom from conformity.
5. The process concludes with a "moderate sense of closure and accomplishment".

It was also suggested that the characteristics of the process which inhibit decision making performance include:

1. A perceived detachment from the problem solving effort attributed to "a lack of socio-emotional rewards in problem solving".
2. Interpretation difficulties amongst respondents as an effect of non verbal feedback.
3. Conflicts may not be resolved.

(Delbecq and Van der Ven 1975, p.35)

The validity of the Delphi Technique as a method of forecasting is challenged by Weaver (cited by Reid *et al.* 1990). He asserted that, in isolation, consensus is not a valid indicator of the plausibility of a forecast. He also challenges the basic assumption of the Delphi Technique. Delphi assumes that individual status affects opinions expressed in group settings and therefore by controlling relevant

psychological factors a more rational judgement would be expressed. Weaver, however, argues that a significant factor is that an individual's decision making strategies change as tasks are perceived to become less ambiguous. This view is supported by Delbecq *et al.* (1975) who demonstrated that interactive groups are more efficient as a means for the clarification of ideas. Although dismissive of the process as a method for forecasting, Weaver does support the process as a technique for the identification of priorities.

6.4.5 CONSENSUS

Hakim and Weinblatt (1993) suggest that stability and convergence can be the criteria that determine the termination of the procedure. Stability describes the similarity of participants' responses across rounds and is measured by the difference in response frequency to each question at successive rounds. They suggest that questions should not be included in subsequent rounds if the response frequency is calculated to be below a determined threshold. Convergence is a reflection of agreement between participants. If the dispersion of responses is found to decrease at successive rounds and falls below a determined threshold, it may be interpreted as indicating consensus. Inversely, an increase in the dispersion of responses indicates disagreement. Hakim and Weinblat (1993) suggest that in such circumstances the exclusion of a question from subsequent rounds should be considered, as pursuing the question further is likely to result in further divergence. Reid *et al.* (1990) even suggested that where a respondent is found to persistently disagree with the opinions of others s/he may be requested to submit a statement defending his or her stance.

The investigation was concluded before a consensus was reached on all groups of criteria. This was in view of the time restraint of the study and concern that the further co-operation of panellists would be affected by protracting the process. These reasons were based on the advice suggested by Delbecque *et al.* (1975). Commitment to the investigation and motivation to comply with the demands of procedure had been exemplary. However, some participants had been submitting contributions to an

earlier Delphi investigation²⁴. It was considered unethical to impose further commitments on these participants. The author suggests, however, that although the seventh task (the ranking of the "Groups of indicators") is limited by a wide dispersion of opinions, the results do demonstrate that there was a convergence of opinions within the 3 highest ranking groups of indicators and that there may be a consensus relating to the criteria recorded in the highest ranked group.

6.4.6 CONTEXTUAL VALIDITY²⁵

It is apparent that the meaning of leprosy in the context of Indian society and culture is profound. The loathing evoked by the disease perpetuates stigma borne not only by those with the disease but also by those who seek to treat either the medical or social consequences of it. This factor has been suggested as a reason why the issue of leprosy continues to have a low priority status among academics and politicians alike (Volinn 1983, Rao 1992). (This issue was discussed in chapter 5.) There are, however, dedicated individuals who continue to endure the frustrations associated with an apparently inefficient administration, flawed with corruption. Such men and women also accept the academic isolation and social frustration associated with the issue of leprosy. The ten Delphi participants who contributed to this study are considered, by the author, to be numbered amongst this select group. The opinions of these individuals will constitute reliable definitions of appropriateness, relative to measures aimed at treating leprosy impairments.

6.4.7 Conclusion

Of the three highest ranking groups of criteria, considered relevant indicators of appropriateness for the treatment of ulceration, two contained lists of criteria that were identifiable features of the results of this study. Although it is the author's

24. A more complex Delphi investigation had been attempted in 1994. This earlier attempt was not successful due to a poor response rate. The investigation was abandoned by December 1995 .

25. Appropriate in a given context. (Moser and Kalton 1977)

opinion that the treatment will meet the "Economic" criteria suggested by the Delphi participants, data to substantiate this claim was not collected. It is suggested, however, that the evidence that has been discussed is sufficient to support a proposal that the treatment was appropriate.

CHAPTER 7

SUMMARY AND RECOMMENDATIONS

"The pathway to amputation of the leg is littered with bandages and dressings which have deceived both doctor and patient into thinking that by addressing an ulcer they are curing it." (Brand 1989)

Impairment control facilitators have escaped from an anachronistic "bandage only" approach. It seems, however, that there has been a loss of momentum where advances in the treatment of plantar ulceration, for the leprosy impaired, are concerned. A pragmatic method was sought to extend the range of ulcer management options available to staff at an Indian leprosy hospital. To assess the effectiveness of the method six parameters were defined and investigated. The findings relating to these parameters have been declared and discussed through this thesis. This chapter considers the salient features, from each aspect of the investigation, and concludes with recommendations.

7.1 EFFICACY

Brand (1992) has expressed reserve in his opinion of orthotic intervention for neuropathic feet. His concern was that improperly placed devices may increase focal pressures and exacerbate ulceration. Whilst recognising this hazard, the results of this study illustrate that orthotic intervention can significantly reduce the duration of ulceration.

It was demonstrated that the duration of ulceration can be curtailed more speedily with orthoses than without. For some, non compliance or poor appliance maintenance frustrated healing. These variables, however, do not detract from the evidence which supports my contention that orthoses can accomplish the objectives for which they are designed.

Appliance maintenance is a significant issue that became apparent in the course of the

project. The integrity of orthoses is dependent on the competence of the footwear that accommodates them. After a period of three months there was a general tendency for sandals to become incompetent as a base structure for the orthoses. There was evidence to demonstrate that whilst three months was an adequate period in which smaller ulcers (1 cm^2) could heal, ulcers with a larger area required more time. If orthoses are to be applied to sandals an essential consideration should be systematic follow up. An initial review, one week after orthoses are supplied should be followed up by monthly reviews, where possible. The minimum requirement should be that patients should be reviewed before a three month period has elapsed following supply. If regular review is not practicable the patient should not be considered suitable for orthotic intervention.

I had postulated that efficacy, in this study would also be demonstrated by reduction in recurrence rates. This proved problematic to demonstrate. There was no valid criterion against which recurrence could be measured. The issue of plantar ulceration, amongst outpatients, is not accorded high priority at Dr Bandorawalla Leprosy Hospital where recourse to hospital records revealed a paucity of information. If ulceration had been recorded the details were generally inadequate with no indication of onset or resolution. The recurrences that were recorded during the experimental period were associated with treatment default. It is possible, however, that for others, recurrence would not have been expected within the study period. The inability to present reliable comparative evidence, on the issue of recurrence, imposes a limitation on support favouring the efficacy of the intervention.

Sensibility Testing

Since this study sought to address the problem of mechanically induced trauma to insensate feet, the determination of pain, pressure and vibration perception was fundamental. Although some investigators have recorded minimal loss of position sense (Jennekens and Jennekens-Schinkel 1992) loss of proprioception, golgi tendon and muscle spindle reflex are not widely reported features of leprosy sensory neuropathy. These modalities did not warrant investigation as they were unlikely to bias results.

Although an exhaustive examination protocol was planned it was deemed not to be necessary to implement it. It was considered that, since all subjects would be "cured" outpatients, it would be sufficient to establish that the feet under examination were all similarly compromised by sensory loss. For this purpose the protocol that was implemented was adequate. This was a rational decision that was consistent with the pragmatic character of the project.

Ulcer Assessment

When designing the ulcer assessment protocol, a significant consideration was that measurement procedures should consider levels of competence and expertise that would be expected from leprosy paramedical workers. This policy was consistent with a project aim; i.e. that it should be repeatable in other leprosy centres. Rao's study has demonstrated the pivotal role of paramedical workers in the implementation of the Indian government's S.E.T. (survey, education and treatment) policy (Rao 1992). A further consideration was that it should be safe and practicable in potentially adverse situations; i.e. outwith a clinical environment. The simple measurement of dimensions demonstrated good inter rater reliability and the calculation of area presented data that did not present any difficulty for comparison and non parametric analysis. As a method for clinical assessment in field conditions this was adequate.

It had been hoped that more detailed data describing tissue responses could be gathered and analysed. This aspect of the assessment procedure was more complex and required more intense attention to observation. The technician was not required to interpret observations but was required to describe them in the same terms as me. This was not difficult to accomplish and, before the culmination of the first assessment, I was satisfied that he and I could describe ulceration in the same terms. This confidence was demonstrated when our findings were correlated following the second assessment.

Although repeatability was reliable, the method did not contribute data to elucidate findings. I concluded that this method of assessment was not a valid instrument to measure changes in ulceration for this study. It may be useful in the evaluation of

more intensive forms of therapy where more rapid results are anticipated and more frequent assessments can be made. However since no firm indication of relationship between the variables was found in this study it was not used in further assessment procedures.

Kinetic effects

I sought to test the hypothesis that podiatric orthoses do reduce peak pressure and PTI at designated sites. I also sought to describe the patterns of redistributed pressure. These objectives were met. Based on the findings presented, it is suggested that there is evidence to support the hypotheses that palliation and moderation of foot function are realised using orthotic techniques. This hypothesis should, ideally, be tested with a sample of symptomatic patients. Such a proposal is problematic as there are wide variations in anatomical, pathological and kinematic variables that would make comparison difficult.

Further study should include an assessment of the effect of intervention on shearing stress. Shear may be quantified directly using the instrumentation reported by Lord (1992). Further study should aim to establish the validity of the inference that shear can be quantified by following the methodology of Katoh *et al.* (1983) or Bransby-Zacchary (1990). Clearly elevated peak pressure has been associated with tissue trauma, but the relationship between peak pressure and shearing stress, as suggested by Brand (1976), remains to be demonstrated.

7.2 ACCEPTABILITY

It has been demonstrated that expensive foot wear or footwear meeting with low patient acceptability is not a prerequisite to successful treatment. The protocol also dictated that all subjects were ambulant, they were not expected to curtail any normal activity and were not further stigmatised as all the devices were discreet. The significance of these observations was that no loss of earnings was experienced during the period under review and no alterations to lifestyle were imposed. These factors may have contributed to the outcome of the study and may be important

considerations affecting the acceptability of the intervention.

Attitude as an indicator of acceptability

Assuming that attitudes are a valid indicator of acceptability it would appear clear that the subjects in the trial were willing to endorse the method favourably. It is my conviction however that the clear enthusiasm to endorse the intervention was based on more than perceived efficacy. The interview schedule was not sufficiently sensitive to enable distinction between attitudes attributable to the orthotic intervention and attitudes to "care". It may be, therefore, that the responses recorded reflect a desire to acknowledge an act perceived to have been highly meritorious rather than the implement used to effect the result.

Clearly, the resolution of the physically and socially debilitating problem of ulceration is certain to bring welcome relief. Orthotic intervention per se can, however, only address the physical pathology associated with ulceration. Whilst pathomechanical foot function does appear to excite ulceration, psycho-social pathology is perhaps a major factor affecting the perpetuation of the problem. Prescribing orthoses, therefore should be considered as an aspect of treatment that can augment patient care. Implicit in the term "podiatric orthoses" is the concept of care which is imbued in podiatric philosophy. The profession of podiatry has not had to reorientate its perspectives from "cure" to "care" because the profession is historically associated with the care of individuals suffering chronic disorders. "Retreatism" has been identified as a stigmatising factor distancing doctors and others from patients with a poor prognosis (Volinn 1983). It is unlikely that retreatism would be characteristic of well-trained podiatrists.

"Patient care" is an acknowledgement of the value of the individual. The positive values in a provider/receiver relationship in a health care environment should be exploited to promote the patient's sense of self worth and human dignity. It should be a priority to promote independence and a sense of personal control. "Treatment" has connotations of concern. Logically therefore "self treatment" (the mainstay of impairment control) is unlikely to be effective until the patient is enabled to perceive

himself as being worthy of concern. This objective is unlikely to be met so long as his/her self perception remains as that of an "ugly untouchable" (Valencia 1988).

Health providers should strive toward assisting the patient to reorientate self perception. Emphasis should be placed on developing dialogue through which self assertiveness could be developed. The self perpetuating image of a piteous object, may be intrinsically pathological and should be ardently opposed. A primary treatment aim should be to present a well-adjusted individual, characterised by a determination to transcend his difficulties in partnership with health providers. Herein lies a dilemma. Those whose efforts to raise an awareness of the effects of the disease, either at a personal or organisational level, have relied on the plight of the sufferer. It is the image of suffering that is exploited to gain sympathy and, consequently, funds. The presentation of the image of leprosy requires a radical transformation. It may be possible, for example, that those presenting with leprosy could be presented as front-line combatants in a confrontation with a disease that threatens societal harmony. Ironically it promotes the image to a heroic struggle with which it may be a duty or a privilege to be associated. It may be though that the image of the "leper", so profoundly inculcated into belief systems, will defy attempts to be destroyed.

The satellite colonies in the vicinity of Dr Bandorawalla Leprosy Hospital could be targeted for more comprehensive study. The author accepts that there are issues considered to compromise the validity of qualitative research (see section 5.2.4.). It is the authors opinion, however, that quantitative analysis cannot convey those aspects of human interaction that are not expressed verbally. Content analysis is less rigid. It is based on the inference and interpretation drawn from unstructured communications (Mostyn 1985). For inference to be valid, interpretation must expose the true meaning of communications. Interpretation, therefore, requires analysis of both manifest and latent data. Essentially, this requires that an analyst should be familiar with the roles, values and lifestyles of the respondents. Such requirements indicate that an ethnographic study would be appropriate. An ethnographic study of these communities could identify the psycho-social variables that affect treatment and treatment response. With such information, more effective health care policies could

be developed.

7.3 IMPLEMENTATION AND SUSTAINABILITY

On the basis of the findings declared in chapter 4, it is suggested that the physiotherapy department was capable of prescribing and supplying orthoses that were at least comparable with those supplied by a podiatrist. An objective of this project was to resource the physiotherapy department with an adjunct to ulcer management. The evidence reported does support the suggestion that this objective was successfully implemented.

It has been demonstrated that it is possible to implement an effective podiatric orthotic service. However for the service to have been sustained and developed contextual factors should have been investigated in greater depth. The prospect of sustainability was weakened due to inadequate insight into the structure and personnel dynamics at the P.D.L.C. and Dr Bandorawalla Leprosy Hospital.

A clearer understanding of the rank and status of interacting personnel and their socio cultural role definitions was a necessary prerequisite that was not adequately addressed in the planning stage of the project. Attention to such details may have facilitated stronger support from influential personnel which may have strengthened the programme structure.

Key project characteristics were considered. On the issue of project integration, it was suggested that the objective of integration into the existing infrastructure was sound. However issues related to staffing within the institution acted to destabilise the continuity of the project.

The difficulties associated with unsuccessfully conducting a "mutually respectful negotiating process" were associated with issues related to contextual factors. Social conventions had been misinterpreted and consequently mismanaged. Once the issue had been diplomatically addressed, however, support for the project from within Dr Bandorawalla Leprosy Hospital developed in enthusiasm.

Personnel training had been a significant factor contributing to the outcome of the project. It was considered that personnel conscientiousness was, in part, due to esteem for the knowledge and skills that were disseminated. External enthusiasm for the project was stimulated partly by the prospect of training other leprosy paramedics. This enthusiasm, supported by published evidence of the efficacy of the approach, contributed to a favourable reputation associated with the project. This reputation may have contributed to the long term sustainability of the approach but developed too late to affect the outcome of the trial.

The demand for continuation of the service by subjects and others who had observed the treatment was not considered to have appreciably affected the sustainability of the project. It is emphasised that the community are leprosy impaired and consequently have low status. As a constituency, their collective voice does not greatly affect the decisions that are made for their welfare.

7.4 APPROPRIATENESS

Of the parameters that were investigated in this study, opinions relating to criteria that constitute "appropriateness" are perhaps the most subjective. Similarly, the evaluation of the intervention as an "appropriate" method, given the context in which the study was conducted, may be biased. The intervention was considered "appropriate" on the strength of my interpretation of associations between the criteria submitted and the findings from the project.

It is ironic that the criteria ranked as most important were those categorised as "sociological" because the literature does not reflect this concern. A fascinating perspective of the reasons for the relative dearth of social science literature on leprosy was suggested by Valencia in her perceptive "State of the Art Lecture" on the social dimensions of the disease (Valencia 1989). It appears that the ancient spectre of leprosy continues to sound its warning bell not only to terrify the ignorant but also to avert the gaze of the academic. It is frustrating that a parallel to the "premature social death" of the afflicted is feared as much by academics as is the physical corruption by

the ignorant. Few social scientists, it seems, are prepared to accept the possible isolation from mainstream contemporary issues that a commitment to leprosy may precipitate. Power and industrialisation, development theories and political economy are areas in which social scientists developing expertise are accorded heightened status and power. As a consequence medical sociology, particularly in developing countries, remains under developed. The attraction of a *Pariah* subject, it seems, must continue to remain predominantly the interest of individualists.

CONCLUSION

Evidence has been presented to support the suggestion that podiatric orthoses are an effective treatment for plantar ulceration amongst subjects affected by leprosy impairment. This appropriate, easily transferable technology demonstrated significant therapeutic advantages and was clearly endorsed by the subjects in the trial.

APPENDIX 1: INTER-OBSERVER RELIABILITY

Seventy four subjects were examined by both observers, A Dey and myself. Ulcer dimensions (the greatest distances longitudinally and horizontally) and observations relating to edge and surface morphology of ulcers were recorded. We conducted the assessment procedures separately. Assessment sheets completed by A. Dey were retained by him until the exercise was complete. On completion of the exercise all data were surrendered to me for calculation and analysis.

Wilcoxon Signed Ranks Test was used to compare findings relating to ulcer area.

$n = 74$

Number of differences ranked = 17

Sum of signed ranks for all differences = 46

Two tailed $P = 0.27$

95% C.I. = 0 to 0

Spearman's Rank Correlation was used to test for relationship between the categorical data (relating to ulcer morphology) collected by A. Dey and those collected by me.

Ulcer surfaces

$n = 74$

Spearman's rank correlation coefficient = 6.1

(The confidence limits for the correlation (r_s) are constructed using Fisher's Z transformation. Arcus tests the null hypothesis that $r_s = 0$.)

95% C.I. = 0.44 to 0.74

Two tailed $P < 0.0001$

Ulcer edges

Spearman's rank correlation coefficient = 6.2

95% C.I. = 0.44 to 0.74

Two tailed $P < 0.0001$

The analysis demonstrated that the differences between findings relating to ulcer area were not significant. The correlations, between the ratings of categorical data recorded by A.Dey with those of mine, suggested a moderate relationship. Had the coefficients been 5 or less a null hypothesis of no relationship between the findings of the observers would have been upheld.

APPENDIX 2: THE INTERVIEW SCHEDULE

Coding: A. Uncertain B. Strongly agree C. Agree
 D. Disagree E. Strongly disagree

Name		Response				
	Question	A	B	C	D	E
1.	When a leprosy patient has an ulcer, it is important to rest his/her foot.	0	2	1	-1	-2
2.	If leprosy patients walk to far they will get an ulcer on their foot.	0	2	1	-1	-2
3.	<i>It is not important that leprosy patients should rub oil into their feet.</i>	0	-2	-1	1	2
4.	It is important that leprosy patients should soak their feet.	0	2	1	-1	-2
5.	<i>It is not important that leprosy patients should have hard skin removed from their feet.</i>	0	-1	-2	1	2
6.	<i>It is not important for leprosy patients to wear leprosy sandals to prevent an ulcer.</i>	0	-2	-1	1	2
7.	In times when they do not have an ulcer it is important for leprosy patients to check their feet for hot spots.	0	2	1	-1	-2
8.	It is important that leprosy patients check foot wear for damage.	0	2	1	-1	-2
9.	<i>It is not important for leprosy patients to have good fitting foot wear.</i>	0	-2	-1	1	2
10.	<i>Footwear from the market is better than leprosy sandals for preventing ulcers/.</i>	0	-2	-1	1	2

11. If leprosy patients have ulcers this size (**2.5cm show diagram**) it is important for them to walk with a stick.

A	B	C	D	E
[0]	[1]	[2]	[-1]	[-2]

12. Leprosy patients should dress all wounds, or only wounds larger than one of the following (**show diagram**).

Undecided	All	.5cm	1cm	2.5cm
[0]	[2]	[1]	[-1]	[-2]

Coding: A. Not applicable B. Daily C. Once a week
 D. Once a month E. Never

		Response				
	Question	A	B	C	D	E
1.	Do you rub oil into your feet?	0	2	1	-1	-2
2.	Do you soak your feet?	0	2	1	-1	-2
3.	Do you have hard skin removed from your feet?	0	2	1	-1	-2
4.	Do you wear leprosy sandals?	0	2	1	-1	-2
5.	Do you wear footwear from the market?	0	-2	-1	1	2
6.	Do you check your footwear to see if it is damaged?	0	2	1	-1	-2
7.	Do you check your feet for hot spots when you have no ulcers?	0	2	1	-1	-2
8.	Do you walk outside your house without footwear?	0	-2	-1	1	2

9. How big would an ulcer be before you would use a stick to walk with (show diagram)?

 Undecided [0] All [2] .5cm [1] 1cm [-1] 2cm [-2]

10. Do you dress all ulcers or only ulcers larger than one of these (show diagram)?

 Undecided [0] All [2] .5cm [1] 1cm [-1] 2cm [-2]

11. If you have an ulcer do you rest your foot?

- A. Undecided.
- B. As much as possible.
- C. I do not often think about resting my foot but sometimes I do.
- D. It does not trouble me so I do not rest it very much at all.
- E. I never rest my foot.

12. If you have an ulcer, how does it affect the distances you walk?

- A. Undecided.
- B. I walk as little and as slowly as possible.
- C. Sometimes I think about walking less and then I use other methods of transport.
- D. It does not trouble me, but I may walk less if someone tells me to.
- E. It makes no difference to the way I walk.

SCORE 11 and 12 A = 0 B=2 C=1
 D= -1 E=-2

Interview Schedule

1. What Important Things Have Happened In Your Life Over The Last Twelve Months?

Event	Very good	Good	Neutral	Bad	Very Bad
Marriages					
Births					
Deaths					
Employment					
Change of housing					
Sickness					
Other					

2. Have You Had Any Problems With The Device?

Problem	Mild	Bearable	Noticeable	Serious	Very serious
Pain					
Discomfort					
Device becoming unstuck					
Difficulty with dressings					
Other					

3. If you think that these devices could be useful, or harmful, for other people, what sort of people do you have in mind?

Probes: Gender, Occupations, Age, size of ulcer, others

[illegible]

4. What did you expect when you were first given the device?

- Probes:
- 1. Was quicker healing expected
 - 2. Was recurrence expected
 - 3. Did subject realise continued use was necessary
 - 4. Did subject expect any other problems
 - 5. Other comments

Expectation	Delighted	Pleased	Acceptance	Disappointed	Annoyed

Record other Comments:

5. Is there anything that especially pleased you about wearing the device, or do you feel that the device is not very useful for you?

- Probes:
- 1. Easy to wear
 - 2. Dressings
 - 3. Problems with device becoming unstuck
 - 4. Was it important which person made the device.
 - 5. Other comments

Feature	Delighted	Pleased	Acceptance	Disappointed	Amoyed

Record other comments:

6. What other things helped or hindered the ulcer to heal?

- Probes:
- 1.Other treatment
 - 2.Prayer
 - 3.Other people
 - 4.Footwear
 - 5.Other

**HEALED ULCERS
ONLY**

Alternative	Great help	Helped	Uncertain	Hinderance	Serious Hinderance

Record Other Comments:

APPENDIX 3:

**THE RECRUITMENT LETTER FOR THE SECOND DELPHI
INVESTIGATION**

Queen Margaret College

EDINBURGH established 1875

Leith Campus • Duke St • Edinburgh • EH6 8HF



Telephone : 0131 317 3000

Fax No : 0131 317 3308

Podiatry and Radiography

Head of Department

Mr P A Shenton DPodM, FChS, SRCh

Direct Dial : 0131 317 3480

Dear

I apologise for this unsolicited letter but request that I may briefly engage your attention. My name is Hugh Cross. I am currently holding a post as a research student in the department of Podiatry and Radiography, Queen Margaret College, Edinburgh. The thesis toward which I am working is entitled "The Efficacy of Podiatric Orthoses as a Treatment for Plantar Ulceration in Leprosy". I have been working with the collaboration of The Poona District Leprosy Committee and staff at Dr. Bandorawalla Leprosy Hospital, Pune, India. Much of the initial data gathering is complete. First indications have been very interesting and I would be delighted to send you details of the project should you be interested.

The principle reason for my approach to you is that I would be very grateful if you would consider offering some assistance in an important aspect of my study.

Contributing to the qualitative support of my study is the inclusion of a programme of surveys and questionnaires that seeks to gauge what constitutes *appropriate* treatment in India. (*Appropriateness* is socially and culturally specific i.e. what is appropriate in Britain may not be appropriate in India.) To accomplish this I am using the Delphi Technique. In the event that you may be unfamiliar with the technique, it is a method by which a consensus of expert views can be recorded on questions relative to the subject of interest. It is conducted on the following lines:

The investigator composes a *Delphi Question* which addresses the research topic.

A *Delphi Panel* then makes responses to the question.

The answers are then collated by the investigator and returned to the *Delphi Panel* who attribute weights to the outcomes expressed.

Responses are analysed and returned to the Delphi Panel for review.

This procedure continues until analysis reveals that there is a consensus, or that no consensus can be reached.

All interaction is by mail and responses for discussion are anonymous.

All contributors are kept informed of developments and results.

The validity of the procedure has been demonstrated extensively, mainly in the field of management and social science.

I am approaching senior Indian medical personnel, experienced in the field of leprosy, with a request for assistance in this aspect of my study. I will be most grateful if you would consider my request to contribute. With this letter, I have taken the liberty of including the Delphi Question. If you are willing to contribute please consider the question and return your responses to me. I would be most grateful if you could respond speedily as this would help the process to be less protracted generally. If you decide not to participate may I thank you for your attention to this letter and wish you a happy and prosperous new year.

Yours sincerely,

Hugh Cross

If you have consented to contribute to this investigation, please consider the following question and give a *maximum of 5* responses to the question. Please record your responses on this page and return it using the envelope provided.

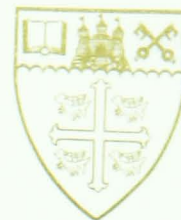
NAME:

**"What Are The Criteria For Measuring Whether Treatment Is
Appropriate For Leprosy Patients In India?"**

Consider only the treatment of complications secondary to nerve damage.

APPENDIX 4:

THE "SECOND ROUND" DELPHI SCHEDULE



Telephone : 0131 317 3000

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Podiatry and Radiography

Head of Department

Mr P A Shenton DPodM, FChS, SRCh

Direct Dial : 0131 317 3480

Re: A Delphi Investigation

**"What Are The Criteria For Measuring Whether Treatment Is
Appropriate For Leprosy Patients In India?"**

Dear

Thank you very much for your responses to the first question of this Delphi investigation. All responses have now been received and I am pleased to inform you that the investigation can continue to the next, and final, round.

The responses were most interesting and wide ranging in their emphasis. There were a total of 38 distinct criteria submitted (as may have been expected some respondents submitted criteria that had been suggested by others). When collating the responses, it became clear that the criteria submitted could be categorised into 6 groups. Since ranking 38 items is problematic, I have categorised the responses. Consequently there are 6 groups with between 4 and 7 responses in each group.

Wherever possible I have presented responses in the form in which I received them. I have altered the wording of responses only where it has been necessary to preserve the logic of the investigation. I have taken care to present the responses in a form which does not compromise their intended meaning.

Please consider the 6 short lists enclosed and rank the responses in each group. I would be most grateful if you could return the completed task to me as soon as possible so that a speedy conclusion can be made and the results can be circulated to all respondents. I will be using the results to augment findings from other investigations I have made.

Yours sincerely

Hugh Cross

Please consider each list and rank the responses according to the importance you ascribe to each suggestion.

Objective criteria indicating "appropriate" treatment

The appropriateness of treatment will be indicated where:	Rank
there is a quantifiable reduction in cracks/callous formation on the plantar surface of the foot.	
the treatment is associated with a reduction in blistering on the plantar surface of the foot.	
the treatment is associated with a return of sweating.	
there is an optimum restoration of nerve function where nerve damage is reversible.	
the treatment facilitates early detection of nerve damage before the damage becomes irreversible.	
there is an improvement in motor power (VMT confirms).	
there is an improvement in sensory perception in the affected parts.	

(1 is the highest rank, 7 is the lowest)

Functional criteria indicating "appropriate" treatment

The appropriateness of treatment will be indicated where:	Rank
there is sufficient mobility for the patient to continue employment without pain or associated swelling of feet.	
there is provision of a long term solution for a current problem i.e. recurrence free results.	
the treatment anticipates other problems likely to arise from the same basic cause (nerve damage) and helps the patient to avoid them.	
the treatment gives optimum restoration of the form and function of the foot when irreversible nerve damage has resulted in deformity and disability.	
the treatment is easy for the patient to comply with.	

(1 is the highest rank, 5 is the lowest)
Psychological criteria indicating "appropriate" treatment

The appropriateness of treatment will be indicated where:	Rank
there is a general improvement in compliance after signs of restoration.	
patient education, regarding the detection and treatment of nerve damage, has been advanced.	
appliances etc. are such that patients can wear them without attracting undue curiosity	
the treatment meets with patient expectations of overcoming stigma	

(1 is the highest rank, 4 is the lowest)
Sociological criteria indicating "appropriate" treatment

The appropriateness of treatment will be indicated where:	Rank
treatment does not interfere with employment or other social/family activities.	
patients and health workers are willing to carry out the treatment.	
the treatment is compatible with available health facilities.	
the patient's quality of life has been improved.	
the treatment helps the patient's family and the neighbourhood to understand and react positively to the patient's predicament.	
there is an infrequent necessity to visit the clinic or workshop (perhaps once in three months).	

(1 is the highest rank, 6 is the lowest)
Economic criteria indicating "appropriate" treatment

The appropriateness of treatment will be indicated where:	Rank
the price is within the gross salary of a hospital employed physical therapist. (This, in India, is currently about Ind. Rs. 750/-, this figure is not to be taken at its exchange value but as the amount equivalent to the salary of the therapist for one week.)	
the treatment is cost effective.	
there is sufficient funding available to implement and sustain the treatment.	
the treatment is practicable in terms of available resources.	
modified footwear is durable (it should last for at least two years).	

(1 is the highest rank, 5 is the lowest)

Epidemiological criteria indicating "appropriate" treatment

The appropriateness of treatment will be indicated where:	Rank
the long term effectiveness of treatment can be efficiently followed up.	
the extent of the problem of preventable disabilities (taking community as a denominator and taking cumulative patient total as numerator) is considered great enough to warrant action.	
a high proportion of patients are satisfied with the available treatment.	
a high proportion of patients avail themselves of the available services.	
a large population of patients, who need services, stay in an area where services are available.	

(1 is the highest rank, 5 is the lowest)

Consider the groups of criteria you have just ranked.
When assessing the appropriateness of treatment for **plantar ulceration**, which of these **groups of criteria** is the most important.

Ranking of indicators of appropriate treatment for plantar ulceration	Rank
Epidemiological indicators	
Economic indicators	
Sociological indicators	
Psychological indicators	
Functional indicators	
Objective indicators	

(1 is the highest rank, 6 is the lowest)

APPENDIX 5:
BIOMECHANICAL EXAMINATION

Date:

Name:

Subject Number:

Non- Weightbearing Foot Examination:

Ankle Joint (R.O.M.)	Normal	Restricted	Excessive
First M.P.J. (R.O.M.)	Normal	Restricted	Excessive
N/A			
Mid Tarsal Joint	Normal	Everted	Inverted
First Ray	Normal	Plantarflexed	Dorsiflexed
N/A			
Fifth Ray	Normal	Plantarflexed	Dorsiflexed
N/A			

Weightbearing Foot Examination:

Subtalar Joint (R.C.S.P.)	Inverted	Vertical	Everted
Subtalar Joint (N.C.S.P.)	Inverted	Vertical	Everted

Gait Examination:

Heel -Toe Gait Pattern	Yes	No
------------------------	-----	----

(If "yes" continue)

Heel Lift	Early	Mid-stance	Late
Subtalar pronation	Heel strike	Mid-stance	Propulsion
Subtalar Supination	Heel strike	Mid-stance	Propulsion
Abductory Twist At Propulsion		Yes	No

APPENDIX 6:
THE CALIBRATION OF THE MICRO-EMED SYSTEM

Calibration Of The Micro-Emed System.

The Micro-EMED calibration device consists of a rubber membrane housed within a secure unit. Compressed air is fed into the device thus exerting a pressure on the inserted insoles. The rubber membrane ensures a homogenous pressure distribution across the entire area of the insoles.

The insoles are first placed in the device and the dynamic amplification and offset procedure is carried out (this is completed by using the Pedar Settings programme produced by, Novel gmbh, Beichstr., 80802 Munich) The procedure optimises the response of all 198 sensors to the whole pressure range, thus ensuring accurate and sensitive measurements. The insoles are then calibrated by loading them through consecutive increasing values of pressure from 4 to 60 n/cm² (using the Micro-EMED calibration programme).

The sensors used in the EMED system are capacitive transducers. A combination of these sensors, arranged in rows and columns, forms a sensor matrix. The columns are vertical strips of metal fixed to one side of a dielectric material, and the rows are horizontal strips of metal fixed on the other side of the material. At each intersection point of the rows and columns there is a capacitive sensor.

A sine signal of constant amplitude and frequency is applied to the columns which act as transmitters. The signal is then transmitted through the dielectric material to be received by the rows. The magnitude of the received signal is a function of the distance separating the rows and columns (or the transmitters and receivers) and hence also of the applied pressure to the sensor matrix.

Where constant pressure is applied to the sensor, an increase in the amplitude of the transmitted signal also produces a corresponding increase in the amplitude of the received signal. An increase in the transmitter amplitude, however, also causes a change in the value recorded for the pressure by the analogue to the digital converter (ADC) of the sensor matrix module. Thus a higher amplification value would result in

an ADC value at a constant applied pressure. There is consequently a higher resolution in the interested pressure range. A change in the transmitter amplitude is produced by electronically multiplying the amplitude of this signal by a specific factor.

Without any application of pressure each sensor has a certain capacitance, and therefore a certain ADC value at a specific amplification. This ADC value is usually half of the value at maximum pressure, which in effect reduces the ADC resolution to half of the maximum range possible, (i.e. a range of 127 to 256 instead of the full range of 0 to 256). In order to counteract the half resolution difficulty, the ADC value at zero pressure is reduced from 127 in order to increase the range of ADC values available and thus increase the resolution of the system (i.e. the offset value is reduced). This is achieved by electronically subtracting a certain amount.

However, the offset and amplification values depend on one another. If the amplification at a certain applied pressure is increased then the ADC value for the unloaded sensor, the offset value, will also be amplified by the same amount. Correspondingly, if the offset value is reduced for the unloaded sensor, then the ADC value for an applied pressure will also be reduced by the same amount. The maximum resolution can be obtained if the ADC value of the unloaded sensor is 0 and that of the loaded sensor, at the maximum pressure of interest, was 255. However, in order to incorporate a safety margin, values of 30 and 240 are taken at no load and maximum pressure respectively, in order to avoid overload and loss of ADC values.

The dependency of the amplification and the offset values on each other makes it necessary to complete an iteration procedure to obtain the best ADC values of 30 and 240. This is started from a definite point of 0 for the offset value and .25 of the maximum for the amplification value. The offset and amplification values are then alternately set, until the maximum range of 30 to 240 is achieved. This procedure is carried out by using the "Settings" programme of the EMED system.

Each sensor within the sensor matrix has specific physical and electrical characteristics which are unique and differ from one sensor to another. With only one

fixed amplification and one fixed offset setting for all sensors, there would be a wide variation in the ADC values at both the lower and upper limits, i.e. with all the sensors unloaded, and with all the sensors loaded to maximum pressure. Owing to this fact, the amplification and offset values must be set for each individual sensor before the pressure value (ADC value) is determined. This procedure is called the "Sensor Dynamic Amplification and Offset Setting" and is the reason why the EMED system is considered to be so accurate in the measurement of absolute pressure.

(Dr. Anna Hayes, **Novel gmbh**, Beichstr., 80802 Munich, is acknowledged for supplying information relating to the calibration of the EMED system.)

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